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An Examination of Awareness of Over-the-Counter Nonsteroidal Anti-Inflammatory Drugs and Adverse Events

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Abstract

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MSM, Boston University, 2001

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Dissertation Submitted in Partial Fulfillment

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Abstract

The elderly population is among the fastest growing populations in the United States. Finding and consuming medications safely and effectively are challenging endeavors for this population. Nonsteroidal anti-inflammatory drugs (NSAIDs) are a widely consumed class of medications among the elderly population, with 70% of individuals consuming over-the-counter (OTC) NSAIDs once a week and 34% using them daily. The purpose of this quantitative study was to determine whether (a) patients are aware of the risks associated with the consumption of NSAIDs, and (b) there are differences in awareness based upon specific demographic characteristics and levels of patient-physician communication. The health belief model (HBM) was used to interpret the results. The HBM is a social cognition framework that takes into account different perceptions, namely, perceived susceptibility of acquiring a health condition, perceived severity of the condition and its consequences, perceived barriers to engaging in the recommended behavior, perceived benefits of engaging in the recommended behavior, and perceived costs of engaging in the recommended behavior. Multiple linear regression was used to analyze the data. The results, which were based upon a cross-sectional survey of 124 participants, showed that the participants' awareness of adverse events associated with NSAIDs use was not associated with sociodemographic variables, rates of consumption, or patient-physician communication. The findings will give the key stakeholders more insight into the issue of preventable adverse events that might lead to the establishment of more safety programs and informatics structural systems to monitor the consumption of OTC NSAIDs and improve lines of communication to protect the elderly population.

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Table of Contents

List of Tables iv

Chapter 1: Introduction 1

Background of the Study 1

Statement of the Problem 10

Purpose of the Study 12

Conceptual Framework 13

Research Questions 15

Definitions of Terms 16

Assumptions of the Study 17

Limitations and Delimitations of the Study 18

Significance of the Study 19

Nature of the Study 19

Summary 20

Chapter 2: Literature Review 21

Literature Search Strategies 21

Self-Care 22

Self-Medication 22

Factors That Determine Attitudes About Medications 27

OTC Medications and Lack of Medical Supervision 29

OTC Medication Consumption and Communication With Physicians 34

Theoretical Framework 47

Summary 54
Chapter 3: Methodology 56
Research Design 57
Sample Selection 58
Sample Size 59
Recruitment Strategy 59
Instrumentation 60
Pilot Test 61
Data Collection 61
Data Analysis 62
Protection of Participants' Rights 63
Summary 64
Chapter 4: Results 65
Sample Demographics 66
Answering the Research Questions 70
Awareness of Risk and Sociodemographic Characteristics 70
Risk and Consumption 72
Awareness and Communication 73
Summary 75
Chapter 5: Discussions 76
Introduction 76
Interpretation of the Findings 78

Support of the Conceptual Framework 83
Recommendations for Future Research 84
Future Research Questions 84
Best Practices to Improve Outcomes 85
Social Change 87
References 88
Appendix A: OTC NSAIDs Survey 102
Appendix B: Permission to Use Instruments 108
Curriculum Vitae 109

List of Tables

Table 1. Research Questions and Statistical Test 63

Table 2. Psychometric Characteristics for the Summated Scale Scores From Pilot Study 65

Table 3. Frequency Counts of Selected Variables Associated With NSAIDs Use 66

Table 4. OTC NSAIDs Categories Used by Highest Frequency 67

Table 5. Frequency Count of NSAIDs Consumption 68

Table 6. Frequency Count of Awareness of Adverse Events Associated With NSAIDs Use 69

Table 7. Descriptive Statistics for Level of Communication Items Sorted by Highest Mean 70

Table 8. Psychometric Characteristics for the Summated Scale Scores 70

Table 9. Pearson Correlations for the Awareness Scale With the Sociodemographic Variables 71

Table 10. Standard Multiple Linear Regression Model Predicting Awareness Level Based Upon Sociodemographic Variables 72

Table 11. Pearson Correlations Between NSAIDs Category Variables and Awareness 73

Table 12. Pearson Correlations for Awareness Scale With Communication Variables 74

Table 13. Stepwise Multiple Linear Regression Model Predicting Awareness Level Based Upon Selected Variables 75

Chapter 1: Introduction

Background of the Study

The elderly population is continuing to grow. In 2009, 39.6 million people representing approximately 13% of the population in the United States, or one in every eight Americans, was over the age of 65 (U.S. Department of Health and Human Services [DHHS], 2011). The DHHS (2011) estimated that by 2030, there will be 72.1 million people over the age of 65 in the United States. The elderly population can find consuming medication safely and effectively a challenging endeavor. Elderly individuals often have one or more comorbidities or chronic disorders that can result in an increased consumption of the number of medications.

Kaufman, Kelly, Rosenberg, Anderson, and Mitchell (2002) reported that in the United States, elderly individuals consume at least one over-the-counter (OTC) or prescribed medication each week and that approximately 25% consume five medications on a weekly basis. Individuals in the elderly population (i.e., age $\geq$ 65 years) are at higher risk than younger adults of experiencing adverse events associated with medications because of age-related physiological changes, possible multiple chronic conditions, and high consumption of prescription and OTC medications (Barkin et al., 2010; Chutka, Takahashi, & Hoel, 2004). Adverse events resulting from taking prescription and OTC medications include falls, cognitive loss, dehydration, incontinence, depression, loss of functional ability, hospitalization, and decreased quality of life (Chutka et al., 2004).

In developed countries, approximately two thirds of individuals ages 65 years and older will at some point take prescription and OTC medications (Mangoni, Jansen, &

Jackson, 2009). Prescribed and OTC nonsteroidal anti-inflammatory drugs (NSAIDs) are the mostly widely used class of medications globally (Kovac, Hourston, & Weinberger, 2010; Lanas & Ferrandez, 2007) as well as in the United States (Abraham et al., 2005). In 2000, the prevalence of self-medication was approximately 92%, and about 55% of OTC medication users consume more than one medication annually (Wertheimer & Serradell, 2008).

Some countries monitor the number of OTC medications purchased and consumed by their citizens. For example, Balbuena, Aranda, and Figueras (2009) reported that the consumption of OTC medications was approximately 46% of the population in Spain and over 60% in Cuba. Balbuena et al. also studied the incidence of self-medication among older urban Mexicans and found that people tended to self-medicate if they lived alone, had low literacy levels, were poorly educated, and/or had a low socioeconomic status (SES). In the United States, OTC purchases are not monitored; therefore, identifying the characteristics of individuals who are the most likely to self-medicate has been difficult. The Balbuena et al. study also revealed that according to a survey conducted in Denmark, there was a greater difference in the use of prescription drugs among individuals with a lower SES, but not in their consumption of OTC medications. Balbuena et al. also reviewed a survey of individuals in the Spanish population that indicated a significant association between self-medication and a higher level of education, gender, lower age, and smoking habit.

There have been insufficient data in the United States regarding the relationship between levels of education, gender, ethnicity, marital status, living arrangements, and

income and OTC medication consumption, including NSAIDs, the most popular class of medications. However, OTC NSAIDs (e.g., acetaminophen, ibuprofen, and aspirin) are the most commonly consumed medications, with 17% to 23% of the population consuming them each week (Fendrick, Pan, & Johnson, 2008). Harris Interactive (2005) completed a survey in the United States of more than 2,000 adults indicating that more than 30% of OTC analgesics are consumed regularly because of chronic pain or arthritis.

According to the National Consumers League (2009), in the United States, more than 175 million people are taking OTC medication for pain. Wilcox, Cryer, and Triadafilopoulos (2005) contended that 36 million Americans are taking OTC pain medications daily and approximately 23 million are taking NSAIDs. Whether medications are prescribed by physicians or purchased OTC, the use of NSAIDs in the United States increases with age (Conaghan, 2012). Based upon the consensus reached by a force that included the American College of Cardiology, the American College of Gastroenterology, and the American Heart Association, 70% of individuals in the elderly population consume NSAIDs once a week, and 34% use them daily (American College of Cardiology Task Force, 2008).

Kaufman et al. (2002) estimated that 80% of adults in the United States will take OTC medications at some point in their lives to relieve pain. Among individuals who consume prescription NSAIDs, Wilcox et al. (2005) reported that almost 50% consume OTC NSAIDs concurrently and that 26% of OTC NSAIDs users consume more than the recommended dosage, as compared to 8% of prescription NSAIDs users. The

consumption of NSAIDs also has been found to be more frequent among female individuals and that it increases with age (Lanas & Ferrandez, 2007).

In a self-medication survey on OTC medications, Neafsey and Shellman (2001) found that 59.3% of the participants reported consuming pain medication 1 month prior to the survey. In addition, 49.5% of the participants reported taking OTC NSAIDs. Of the participants who reported NSAIDs consumption, 46.9% reported taking NSAIDs for pain for 3 or more days at a time, and 36.7% reported taking NSAIDs daily for pain (Neafsey & Shellman, 2001).

The high rate of consumption of NSAIDs relates to the belief that they are safe (Neafsey & Shellman, 2001). Individuals consume OTC medications inappropriately because they believe that these medications are safe. The inappropriate use of medications among the elderly population is particularly important to understand because of their increased risk of adverse events. The elderly population might consume these medications in doses that are higher than recommended or in combination with other medications that can elevate the risk of adverse events (Fendrick et al., 2008). At least 25% of patients consuming NSAIDs experience adverse events, and many of these patients require medical attention or possible hospitalization (Lanas & Ferrandez, 2007).

NSAIDs are one of the most common causes of reported serious adverse reactions to drugs that can involve the gastrointestinal tract, cardiovascular system, liver, and kidneys (Barkin et al., 2010; Pineles & Parente, 2012). The risk of adverse events increases not only among the elderly population but also among individuals who have been diagnosed with comorbid conditions. For instance, acetaminophen, a common

analgesic in the United States, has been reported as causing 78,414 emergency room visits and 26,000 hospital admissions annually (Budnitz, Lovegrove, & Crosby, 2011; Lee, 2007; Nourjah, Ahmad, & Karwoski, 2006). Acetaminophen overdose also has been linked to approximately 100 deaths annually in the United States (DHHS, 2009).

The high prevalence of NSAIDs use among patients who are at risk of experiencing significant adverse drug-related events or who have chronic disease states that contraindicate NSAIDs consumption also is a major concern (Adams et al., 2011). Approximately 75% of the individuals who consume NSAIDs have one or more comorbidities that include cardiovascular disease, hypertension, or chronic kidney disease. For example, 50% of the people who consume NSAIDs have a diagnosis of hypertension, and an additional 33% have a diagnosis of Stage 3 or higher chronic kidney disease (Adams et al., 2011). In addition, 20% of individuals with cardiovascular disease have reported consuming NSAIDs (Adams et al., 2011). Cebollero-Santamaria et al. (as cited in Mangoni et al., 2009) found that bleeding from a peptic ulcer was associated with the use of NSAIDs in 81% of 84 patients in their study and that 95% had purchased OTC NSAIDs.

In the Nurses' Health Study 1, an 8-year follow-up study, Dedier et al. (2002) surveyed more than 51,000 nurses and found that the risk of developing hypertension increased with the frequency of NSAIDs use. Conaghan (2012) reported that NSAIDs consumption can be associated with an increased risk of cardiovascular events such as myocardial infarction, heart failure, and hypertension that is dependent upon the duration

of exposure. Conaghan further suggested that the consumption of NSAIDs can result in gastrointestinal complications in approximately 10% to 30% of patients.

The public health research about NSAIDs consumption has focused on the rates of consumption among the elderly population as well as the associated risks of adverse events (A. Johnson, 1998; Taylor, Lemtouni, Weiss, & Pergolizzi, 2011). According to A. Johnson (1998), the prevalence and incidence of hypertension increase with age, a finding that more recent statistics have supported (Barkin et al., 2010). Thirty-three percent of adults in the United States have been diagnosed with hypertension, a major risk factor for cardiovascular disease morbidity and mortality (Neafsey, Strickler, Shellman, & Chartier, 2002). Overall, A. Johnson asserted that approximately 15% of individuals in the elderly population consume at least one NSAID and an antihypertensive medication, which means that in the United States, nearly 20 million people consume antihypertensive medications and NSAIDs concurrently.

A large case study by Medicaid compared 9,411 patients who were taking antihypertensive medications to a control group of 9,629 patients who were not taking antihypertensive medications and found that patients who were taking NSAIDs were at increased risk of having to take antihypertensive medications than individuals who were not consuming NSAIDs (as cited in A. Johnson, 1998). In addition, the adjusted odds ratio (OR) for age, gender, and body mass index (BMI) further increased when consumption of the daily dosage also increased. For example, among patients who consumed high dosages of NSAIDs, the relative risk of antihypertensive medication initiative was 1.8 times greater than among individuals who were not taking NSAIDs,

and the proportion of new antihypertensive treatment attributed to the use of nonaspirin NSAIDs was about 10% of the cohort (as cited in A. Johnson, 1998). Patients who consumed NSAIDs and antihypertensive medications had a systolic blood pressure that was greater than 140 mm Hg, as compared to those who were consuming only antihypertensive medications (as cited in A. Johnson, 1998). A systolic blood pressure $\geq$ 140 mm/Hg and/or a diastolic blood pressure $\geq$ 90 mm/Hg is considered hypertension (Adams et al., 2011). Seven million deaths occur worldwide annually that are the result of a diagnosis of hypertension; in the United States, approximately 73 million people have been diagnosed with hypertension (Aljadhey et al., 2012). The question becomes one of asking how NSAIDs affects the incidence of hypertension.

Aljadhey et al. (2012) completed a retrospective cohort study to determine the effect of NSAIDs on systolic blood pressure. They collected data from the electronic medical records of 1,340 participants in Indianapolis, Indiana. The results showed that NSAIDs had an impact in increasing systolic blood pressure from 2 mm/Hg to 5 mm/Hg, depending on the NSAIDs consumed. An epidemiological study of 2,805 people over the age of 60 years (adjusted for age, gender, BMI, coronary heart disease [CHD], smoking, and alcohol consumption) indicated that NSAIDs use could significantly predict the presence of hypertension OR = 1.4 (95% C.I., 1.1-1.7) among individuals in the elderly population (L. Johnson, Simons, Simons, Friedlander, & McCallum, 1993) because the effect is elevated within this patient population.

Forman, Rimm, and Curhan (2007) completed a retrospective case, controlled study that evaluated the consumption of acetaminophen, NSAIDs, and aspirin in male

individuals. The results showed that the consumption of acetaminophen 4 to 5 days/week was associated with an increased risk of hypertension (relative risk [RR] = 1.59; 95%, CI 1.13-2.24). If NSAIDs consumption increased to 6 or 7 days/week, there was a simultaneous increase in the risk of hypertension (RR = 1.38; 95%, CI 1.09-1.75). The use of aspirin 2 or 3 days/week also increased the risk of hypertension (RR = 1.36, 95%, CI, 1.14-1.61; Forman et al., 2007). The Rural Health study involved a sample of 3,117 people over the age of 65 years (Cornoni-Huntley, Brock, & Ostfeld, 1986). The results of that study showed that participants who consumed NSAIDs also were taking antihypertensive medications and had a mean systolic blood pressure 4.9 mm/Hg higher than nonusers.

Elevated blood pressure puts people at risk of adverse cardiac events. Guidelines from the American College of Cardiology and the American Heart Association have recommended not prescribing NSAIDs to patients who have had a myocardial infarction (as cited in Boyle, 2011). The consumption of NSAIDs (e.g., celecoxib, rofecoxib, diclofenac, ibuprofen, or naproxen) following a myocardial infarction has been associated with a 50% increased risk of death as well as an increase in combined endpoint of death or myocardial infarction (Boyle, 2011). As a result, there has been some evaluation of replacing NSAIDs treatment with alternatives such as fish oil (Maroon & Bost, 2006); avocados; or soybeans (Ernst, 2003). Current guidelines for NSAIDs therapy suggest that they should be used for the shortest time possible (Boyle, 2011).

The consumption of NSAIDs and OTC medications is a major clinical concern. Because NSAIDs help to alleviate pain, the rates of consumption and misuse of NSAIDs

might lead to unnecessary illness and potentially adverse events. NSAIDs counteract the effects of commonly prescribed antihypertensive medications such as beta-blockers, angiotensin receptor blockers (ARB), and angiotensin-converting inhibitors by destabilizing blood pressure (Singh et al., 2003). The Framingham Heart Study and the Systolic Hypertension in the Elderly Program reported that increases in blood pressure correlate with an increased frequency of cardiovascular events (as cited in Singh et al., 2003). A continued increase in blood pressure can lead to a higher risk of ischemic and hemorrhagic strokes, ischemic cardiac events, and congestive heart failure (White, 2009). The potential destabilization of blood pressure by NSAIDs can occur in less than 2 weeks from initiation of therapy (White, 2009). Improving health outcomes among the elderly population is possible when additional factors such as increasing patient knowledge and behavior compliance through effective patient-physician communication is considered.

The quality of health care and the levels of communication between physicians and patients are related to patient outcomes (Funnell, 2011; Ratanawongsa et al., 2008; Verlinde, De Laender, De Maesschalck, Deveugele, & Willems, 2012). Physician communication should include active listening, use of open-ended questions, nonverbal cues, and acknowledgment of and empathy toward patients' emotions (Funnell, 2011). The communication styles of physicians will correlate to patients' medication consumption behaviors; levels of trust with their physicians (Funnell, 2011; Verlinde et al., 2012); and levels of satisfaction, compliance, and recall of medical information.

Open and honest communication also is linked to improved outcomes related to emotional health, functioning symptom resolution, and blood pressure and/or blood sugar

control (Ratanawongsa et al., 2008). When patient-physician communication is poor, the risk of adverse events with patients increases. Patients and physicians need to take equal responsibility to improve the lines of communication to ensure that they are honest, open, informative, and bidirectional (Bezreh, Laws, Taubin, Rifkin, & Wilson, 2011).

The U.S. Food and Drug Administration (FDA) changed labeling requirements for NSAIDs to include warnings about the consumption of this class of medications, namely, stomach bleeding and liver toxicity (as cited in DHHS, 2009). In the United Kingdom, consumption quantities of OTC analgesics have been controlled since 1998, but there has been a lack of control regarding who can purchase OTC analgesics in the United States that has put people at risk of misuse and adverse events (Pineles & Parente, 2012).

Statement of the Problem

The extended life span has been the result of awareness of disease states, improved compliance with preventative medicine, the use of enhanced technology, and a concomitant expansion of an aging society (Beyth & Shorr, 2002; Lipschitz, Shmookler Reis, & Sullivan, 2001). People are taking more responsibility for their medical conditions, including self-diagnosing and self-medicating. More than 175 million adults in the United States consume OTC medications primarily for pain relief (National Consumers League, 2009). One of the most commonly consumed groups of OTC medications is NSAIDs.

Individuals ages 65 years and older account for over 30% of prescription medication users and 50% of OTC medication users (Beyth & Shorr, 2002). The average

number of prescribed and OTC medications consumed by individuals in the elderly population in the United States is six/day; this amount increases to nine/day if the individuals are institutionalized (Heuberger, 2012). OTC analgesics are generally well tolerated and effective, but their long-term use could result in adverse effects. Seager and Hawkey (2001) reported that as of 2001, 16,500 people died annually and 103,000 were hospitalized because of NSAIDs-related complications. These statistics have remained constant as mortality estimates of NSAIDs-related deaths in the United States have continued to increase (Cryer, 2005).

Neafsey and Shellman (2001) concluded that over 40% of people have the misconception that OTC drugs are weak and not harmful. In order to make effective decisions, individuals need to understand the risks and benefits of taking OTC NSAIDs. Despite the high prevalence of OTC NSAIDs use among elderly individuals, the extent to which these users are aware of the association between NSAIDs use and adverse outcomes is unknown. Although patients want to be educated about the possible side effects of medications (Papanikolaou & Ioannidis, 2003), physicians are reluctant to inform patients about the possible side effects of consuming some medications, particularly medications that have a low risk of adverse events. The side effects of NSAIDs in the United States and across the global community have become a major concern.

International researchers have expressed concern about the safe and effective consumption of NSAIDs as well as the increased risk of adverse events among individuals in the elderly population because of physicians' lack of communication with

patients about the safe use of NSAIDs (Motola et al., 2004). Papanikolaou and Ioannidis (2003) conducted a survey in Chalki, Greece, to evaluate the population's awareness of side effects associated with medication consumption. The results showed that personal experience with adverse events was the strongest correlation of the awareness of side effects. If the individuals had not experienced any direct side effects from their medications, they had decreased levels of awareness of side effects.

In the United States, a gap exists in the literature in understanding the importance of patient-physician communication about OTC NSAIDs consumption and levels of awareness of adverse events. Gaining more information about the relationship between the demographic characteristics of individuals who are or who are not knowledgeable about the adverse outcomes and consumption of OTC NSAIDs, along with the level of patient-physician communication, might make a difference in identifying the individuals who might be at risk and what factors increase that risk among the elderly population. Most studies have focused on adverse events related to prescription medications and have not evaluated the ways in which sociodemographic characteristics and communication levels between physicians and patients impact the consumption of OTC medications, especially NSAIDs.

Purpose of the Study

The purpose of this study was to determine whether patients are aware of the risks associated with the consumption of OTC NSAIDs and whether differences in awareness are based upon specific demographic characteristics. In addition, I sought to identify the

extent to which patient-physician communication levels influence patients' awareness of adverse events.

Conceptual Framework

Individuals' attitudes and beliefs can help to explain their health behaviors (Boskey, 2008), which depend on the values that the individuals place on particular goals and the likelihood that given actions will achieve those goals (Galvin, 1992). The health belief model (HBM) is a social cognition framework used when studying health behavior (Hochbaum, 1958; Shanks, 2009; Thompson & Caltabiano, 2010). The HBM takes into account different perceptions, namely, perceived susceptibility of acquiring a health condition, perceived severity of the condition and its consequences, perceived barriers to engaging in the recommended behavior, perceived benefits of engaging in the recommended behavior, and perceived costs of engaging in the recommended behavior (Shanks, 2009; Thompson & Caltabiano, 2010).

The HBM was the theoretical framework of the current study. This model focuses on the knowledge, attitudes, and beliefs of individuals. In other words, the basis for the model is to help people to access and manage their health in regard to preventing illness or health problems because health behavior is impacted by the beliefs or perceptions that a negative health condition (e.g., cardiovascular adverse event) can be avoided (Glanz, Lewis, & Rimer, 2002). Self-medication is an important part of patients' medical behavior. It usually is the first choice for the treatment of the early symptoms of disease. The risk associated with using any medication inappropriately is that it can do more harm than good. In addition, a suggested treatment plan or intervention can be implemented

when an individual has a positive expectation that if the health action is followed and maintained, the risk of illness or disease can be avoided (Boskey, 2008).

The HBM has been used to motivate individuals to choose positive health behaviors by increasing their awareness of side effects and subsequently decreasing the occurrence and severity of health complications (Glanz et al., 2002). The HBM was chosen for this study because previous use of the HBM has been found effective in identifying readiness to engage in a health behavior because of a perceived threat of disease, susceptibility of disease, potential severity, and benefits and barriers (Glanz et al., 2002; Hochbaum, 1958).

I examined differences in the perceived severity of adverse events resulting from OTC NSAIDs use and perceived susceptibility of adverse events resulting from consumption. The choice to consume OTC NSAIDs might be dependent upon beliefs about the perceived outcomes of behavioral changes. This behavior also might be influenced by individuals' attitudes toward behavioral changes and whether they understand the perceived severity of the adverse effects of OTC NSAIDs consumption, which might result in behavioral modification. Attitudes toward medications are linked directly to the perceived need for drug treatment. With support from the HBM, education and knowledge can impact individuals' attitudes and behaviors (Isacson & Bingefors, 2002; Wertheimer & Serradell, 2008).

The HBM has been used to examine the influence of physician communication on patients' health care regimens (Bezreh et al., 2011). Health communication might be a way to improve awareness, knowledge, and health behaviors. Increasing patients'

awareness of the perceived susceptibility of an adverse event related to the consumption of OTC NSAIDs might help to reduce or prevent such adverse events. The HBM helped to examine possible associations between rates of use and perceptions of risk associated with use. A lack of communication between physicians and patients creates a gap in knowledge transfer and puts patients at increased risk of preventable adverse events. This gap in communicating medical information can result in a lack of awareness and understanding of the true risks associated with the inappropriate consumption of OTC NSAIDs. The HBM posits that perceptions of risk can impact behavior, so I sought to determine whether physician communication is one area where perceived risk associated with OTC NSAID use might be impacted.

Research Questions

Three research questions and hypotheses guided the study:

1. To what extent does the awareness of the risk of adverse events associated with OTC NSAIDs use vary by sociodemographic characteristics among the elderly (SES, race/ethnicity, gender, and education)?

H_{01}: There is no significant difference between awareness of the risk of adverse events associated with OTC NSAIDs use and sociodemographic characteristics among the elderly population.

H_{a1}: There is a significant difference between awareness of the risk of adverse events associated with OTC NSAIDs use and sociodemographic characteristics among the elderly population.

2. To what extent does awareness of the risk of adverse events associated with OTC NSAIDs consumption vary by rates of OTC NSAIDs consumption among the elderly population?

H_{02}: There is no significant difference between awareness of the risk of adverse events associated with OTC NSAIDs consumption among the elderly population.

H_{a2}: There is a significant difference between awareness of the risk of adverse events associated with OTC NSAIDs consumption among the elderly population.

3. To what extent are levels of awareness of adverse events associated with OTC NSAIDs consumption and levels of communication with their physicians among the elderly population?

H_{03}: There is no significant difference between awareness of adverse events associated with OTC NSAIDs consumption and the level of communication with physicians among the elderly population.

H_{a3}: There is a significant difference between awareness of adverse events associated with OTC NSAIDs consumption and the level of communication with physicians among the elderly population.

Definitions of Terms

Attitude: "Learned predisposition or tendency on the part of an individual to respond positively or negatively to some object, situation, concept or another individual" (Goswami & Mahanta, 2012, p. 2).

Health belief model (HBM): A social cognition framework that studies health behavior; includes elements of an individual's perceptions or beliefs influencing whether or not a health action will be initiated or avoided to prevent disease or illness (Hochbaum 1958; Shanks, 2009; Thompson & Caltabiano, 2010).

Perceived barriers: The potentially negative obstacles that might discourage behavioral changes (Thompson & Caltabiano, 2010).

Perceived benefits: The benefits of behavioral modification (Galvin, 1992; Thompson & Caltabiano, 2010).

Perceived severity: The feelings associated with seriousness in terms of health (disability or death) and social consequences (job or family; Shanks, 2009).

Perceived susceptibility: Is the subjective perception of the likelihood of experiencing health complication/s or conditions (Shanks, 2009).

Self-care: The care taken by individuals towards their own health and well-being; encompasses the actions needed to lead a healthy life; meet social, emotional, and psychological needs; care for a long-term condition; and prevent further illness (Fredericks & Sidani, 2012).

Self-efficacy: The confidence to participate in behavioral change (Noroozi, Jomand, & Tahmasebi, 2011).

Assumptions of the Study

I made two assumptions:

1. The participants would represent the target population.

2. The participants would respond honestly and openly to the survey (see Appendix A) questions so that their responses would reflect real perceptions. The participants were advised that there were no right or wrong responses.

Limitations and Delimitations of the Study

A questionnaire facilitated collection of the data. There was a risk of recall bias in that the knowledge, attitudes, and behavioral patterns reported by the participants might have affected the precision of the data because of concerns remembering former behavioral actions in regard to the consumption of OTC NSAIDs. The participants also could have demonstrated reporting bias. In addition, the questionnaire focused on only a few side effects resulting from the consumption of OTC NSAIDs, so there was the potential for other risks that the participants might not have been aware of as well as risks that the questionnaire items did not mention. Another limitation was that the participants could have experienced asymptomatic side effects, meaning that the number of side effects could have been higher than they might have been willing to reveal.

In addition, I did not include prescription NSAIDs use, which is relatively common in the elderly population. Furthermore, the questionnaire did not include the collection of information about comorbidities, including medical conditions for which NSAIDs use is essentially universal (e.g., rheumatoid arthritis or osteoarthritis). Other comorbidities that were considered were cardiovascular disease and aspirin used for cardiovascular disease prophylaxis and asthma, especially when discussing risk of asthma attack.

Significance of the Study

Knowledge of the population and patterns of OTC NSAIDs consumption among the elderly will help to identify groups using the medications, and this knowledge can be used to develop educational interventions (Wilcox et al., 2005). Such knowledge will help to bridge the gap between physicians and policymakers, which might then lead to the development of intervention programs at the local, national, and international levels. Improved targeting specific to the extensive consumption of OTC NSAIDs by elderly individuals will increase the awareness among this population about the side effects of these medications. In addition, researchers have identified differences in self-medication among health care settings and countries, thus emphasizing the need for studies at the local level to analyze patterns of self-medication in order to identify key elements for future interventions to minimize this public health problem. It is important to understand how physicians and patients discuss the consumption of OTC NSAIDs because better communication between physicians and patients might help to facilitate the early detection of potential drug-drug interactions, identify issues in regard to the duplication of therapeutic medications, and develop treatment plans to improve and/or maintain patients' health.

Nature of the Study

This quantitative, cross-sectional study used a convenience sample of participants ages 65 years and older recruited from activity centers and independent living facilities for senior citizens in a metropolitan area in the Midwestern United States. Data were collected using a survey of questions from two validated instruments: the OTC Pain

Reliever Survey (Cham, Hall, Ernst, & Weiss, 2002). and the Perceived Efficacy in Patient-Physician Interaction Questionnaire (Maly, Frank, Marshall, DiMatteo, & Reuben, 1998). Data were analyzed using SPSS. Multiple linear regression was used to examine the relationships between sociodemographic characteristics and awareness of adverse events associated with OTC NSAIDs consumption, OTC NSAIDs consumption and physician-patient communication, and physician-patient communication and awareness of elderly individuals of the risk of adverse events associated with OTC NSAIDs consumption.

Summary

This chapter included an explanation of the concepts associated with OTC NSAIDs consumption, adverse events, and physician-patient communication. Chapter 2 provides a literature review of previous research associated with NSAIDs consumption and helps to identify gaps in the literature that led to the formulation of the research questions. Chapter 3 provides a description of the methodology that includes information about the study design, sample, and data analysis. Chapter 4 presents the results of the data collection and analysis processes. Chapter 5 includes my interpretation of the results based upon the current literature and theoretical framework as well as recommendations for future research.

Chapter 2: Literature Review

Literature Search Strategies

This chapter presents a review of the literature on knowledge and awareness related to the consumption of OTC NSAIDs. The purpose of this study was to (a) identify the relationship between the consumption of OTC NSAIDs and the knowledge and awareness of the elderly population about adverse drug events, and (b) understand the impact of patient-physician communication on the consumption of OTC NSAIDs by elderly individuals. The chapter presents a review of the literature on self-medication behaviors, the consumption of OTC NSAIDs related to sociodemographic characteristics and lines of communication between physicians and patients, and the side effect profile of OTC NSAIDs.

A review of the literature was conducted using the Sage Online Journals, Medline, Google Scholar, Academic Search Premier, CINAHL, ProQuest, and PubMed databases. Key words in the search for relevant literature included *NSAIDs*, *over-the-counter medications (OTC)*, *side effects*, *socioeconomic status (SES)*, *gender*, *health belief model*, *self-medication*, *communication*, and *physicians/health-care professionals*. The review comprised more than 90 articles published between 1992 and 2013 that addressed prescription NSAIDs and OTC NSAIDs. Several themes emerged from the literature review, namely, self-care and self-medication, the latter of which is becoming a larger public health concern because it can result in significant economic and social implications for the health care system in particular and society in general.

Self-Care

The purpose of self-care by individuals, families, and communities is to establish and maintain health, prevent disease and illness, and control current medical conditions (Baig, Muzaffar, Afaq, Bilal, & Iqbal, 2012; World Health Organization [WHO], 1998; You, Wong, Chan, Wong, & Yeoh, 201l). Taking responsibility for personal well-being can involve changes in behaviors related to hygiene, nutrition, and lifestyle while also taking into account environmental factors, SES factors, sociodemographic factors, and self-medication factors (Baig et al., 2012; WHO, 1998). Self-care is the engagement in activities that are learned and are meant to promote healthy functioning that is the result of beliefs; health status; and sociodemographic characteristics (e.g., age, gender, culture, education, and marital status) and traits (Fredericks & Sidani, 2012). Individuals learn self-care behaviors within a sociocultural context, meaning that these behaviors are influenced by values and goals and are executed based upon ability. The components of ability include not only knowing what is available but also understanding the effectiveness and desirability of actions, judging the options available in the course of self-care behavior; and having the necessary resources (i.e., physical, psychological, emotional, and material) available to make behavioral changes (Peters & Templin, 2010). One example of self-care is self-medication, particularly the use of OTC medications.

Self-Medication

According to the WHO (1998), self-medication is the selection and use of medicine to treat self-recognized illnesses or symptoms. Afolabi (2012) estimated that approximately 50% to 75% of health care expenses are associated with self-medication.

Self-medication represents an area of health care in which patients assume more responsibility by using pharmaceutical products that are available to them without prescriptions from physicians (Hughes, McElnay, & Fleming, 2001). However, self-medication is not without risks, despite the advantages associated with patient empowerment (Hughes et al., 2001). People might choose to self-medicate to treat current medical illnesses whose treatment regimens might include prescription medications as well as OTC medications, both of which are safe and effective when used as directed (WHO, 1998). However, people who choose to self-medicate must be sure that the medications are appropriate for their chronic or recurrent conditions and have proven records of safety, quality, and efficacy (WHO, 1998). These products should include information describing how to take or use the medications, possible side effects or interactions, how the effects of the medicine should be monitored, precautions and warnings, duration of use, and when to seek advice from physicians (WHO, 1998).

When individuals choose to self-medicate, they take medication without consulting their physicians and might not even be willing to seek correct information about the appropriate doses or duration of the medication (Baig et al., 2012). When individuals choose to self-medicate, they are engaging in help-seeking behavior (Klemenc-Ketis & Kersnik, 2011). In order to self-medicate appropriately, people must identify their symptoms accurately; create therapeutic objectives; choose the correct medications, which includes dosage and timing; and take into account their past medical histories, drug contraindications, and possible side effects (Auta, Omale, Folorunsho, David, & Banwat, 2012). Other factors that can influence self-medication practices

include gender, income, self-care orientation, and medication knowledge (Martins et al., 2002).

Taking ownership of their health and well-being gives people the opportunity to take responsibility for and build confidence in their ability to manage their own health status (Hughes et al., 2001). Patient empowerment helps patients to improve their levels of awareness and also supports the development of positive relationships with their physicians. Hughes et al. (2001) reported similar results in other studies indicating that patients found nonprescription or any OTC medication more convenient, effective, and economical. Hughes et al. collected data from the British Market Research Bureau International from approximately 2,000 people about their use of nonprescription medications. The data analysis indicated that 80% of the participants felt that it was important to use nonprescription medicines for minor health problems, 67% reported that such medicines were just as effective as those obtained from doctors, and 86% stated that they would purchase again the same medication that they had used previously. These results suggested that the public has confidence in self-treatment as well as the convenience and effectiveness of medications that are available without physicians' prescriptions (Hughes et al., 2001).

Approximately 60% to 80% of health problems in developing countries are now being treated through self-medication regimens (Auta et al., 2012). A cross-sectional survey of 1,000 Slovenian adults ages 18 years and older was conducted by Klemenc-Ketis and Kersnik (2011) to gain insight into when the participants chose to self-

medicate. The results showed that 77.2% of the participants chose to self-medicate when they first identified symptoms.

Despite the convenience of purchasing OTC medications, the health care system cannot monitor these purchases effectively enough to impact patient care and OTC medication consumption. As a result, it has become challenging to collect data on the use of OTC medications such as NSAIDs because they are usually not reported or documented (Kovac, Saag, Curtis, & Allison, 2008). Most data on the consumption of OTC medications have been obtained from outside of the United States. Guirgis (2010), for example, conducted a retrospective cohort study of 51 patients in Australia to examine the prevalence of the consumption of OTC products by chronically ill patients. Guirgis found that 80% of the patients with chronic conditions used OTC products and did not follow the directions on the package inserts.

Baig et al. (2012) conducted a quantitative, cross-sectional study to determine the prevalence of and factors associated with self-medication among 400 dental patients visiting an outpatient dental department from March to May 2010 at Fatima Memorial Hospital in Pakistan. The results gleaned from the questionnaire responses showed that the prevalence of self-medication was 70.8%, high in comparison to studies in China (32.5%), India (34.5%), and Turkey (45%), but low in comparison to studies in Sudan (73.9%) and Kuwait (92%; Baig et al., 2012). Furthermore, Baig et al. reported that 66.4% of their participants who self-medicated were female.

Solomon (2003) completed a study in Nigeria whose results showed a high prevalence of self-medication among female individuals (61.9%); Angeles (as cited in

Solomon, 2003) found the same results in a study in Mexico (46%). The level of education documented by Baig et al. (2012) showed that 28.4% of graduates self-medicated. Of the participants who graduated, 57% stated that self-medication was an option as a treatment regimen to avoid unnecessary dental care, 40% considered cost in the decision to self-medicate, 55.6% self- medicated because of a lack of time, and 52% self-medicated because of a dental phobia (Baig et al., 2012). According to Afolabi (2012), individuals who have chronic conditions such as asthma will self-care for months and years, with 48% of these individuals buying OTC medications as a prophylaxis. Afolabi also reported that of the individuals known to have frequent migraines, approximately 42% will self-treat rather than seek treatment from their physicians and that in Canada, 90% of individuals suffering from migraines will use OTC medications.

In most developing countries, self-care medications can be purchased without physicians' prescriptions. For example, in Ecuador, 51% of medication sales are OTC, 66.3% in the Philippines, and 80% across the United States-Mexico (Afolabi, 2012). In countries where OTC medications are regulated, the percentage of nonprescription sales is approximately 26.2% (Afolabi, 2012). Researchers have published very few studies evaluating the use of OTC medications and OTC NSAIDs specifically. Antonov and Isacson (1996) conducted a study in Sweden showing that the use of analgesics was common among people reporting chronic pain. Female participants who reported chronic pain consumed more analgesics and sedatives than the male participants did. Besides female gender, self-perceived poor health, high pain intensity, insomnia, physician

consultation, and self-care action helped to explain medication with analgesics (Antonov & Isacson, 1996).

Factors That Determine Attitudes About Medications

Self-care orientation and medication knowledge are important factors in determining attitudes toward the consumption of medications (Isacson & Bingefors, 2002). There has been an ongoing increase in the number of people who are taking responsibility for their own health because of SES factors (e.g., empowerment over personal health, improved educational levels, and access to information); lifestyle choices; ready access to medications; increased potential to manage certain illnesses through self-care; public health and environmental factors; greater availability of medicinal products; and demographic and epidemiological factors (Baig et al., 2012; WHO, 1998). Taking responsibility also can depend on sociocultural and personal factors, which might help to explain why people have different reactions to illnesses and different ways of handling their self-medication (Klemenc-Ketis & Kersnik, 2011).

However, if individuals do not take responsibility for their self-medication regimens, they are at risk of consequences that include, but are not limited to, bacterial resistance, masking of symptoms or illness that can delay treatment, and decreased efficacy of medications because of wrong dosages or duration (Balbuena et al., 2009). Furthermore, cultural and religious beliefs can sometimes create additional risks related to self-medication (Balbuena et al., 2009). In an observational, cross-sectional study of 245 participants ages 65 years and older in Chiapus, Mexico, Balbuena et al. (2009) evaluated the consumption of OTC medications and additional factors that might have

affected the participants' decisions to self-medicate. More than 50% of the participants consumed OTC medications within a 30-day period. Self-medication was significantly higher among the participants who lived independently than among the married couples (p = .0274) as well as those who were illiterate or had low educational levels than among participants with secondary school degrees (p = .0036); 26.7% of the participants reported adverse events.

Other factors such as level of education and SES might impact individuals' knowledge of OTC medications. Inequities in health care, including the consumption of OTC medications, continue to be a public health challenge (Hosseinpoor, Williams, Itani, & Chatterji, 2012). Globally, SES, as measured by education, income, or occupation, is associated with poorer health status (Hooseinpoor et al., 2012). Hosseinpoor et al. (2012) used the health domains of mobility, pain, sleep cognition, and vision developed by the WHO to assess SES inequalities in these domains and their relationship to self-care. In the study, self-care was defined as the care taken by individuals to enhance their own health, prevent disease, limit illness, and restore health and well-being. In practice, self-care includes actions to stay fit and maintain good physical and mental health, meet social and psychological needs, prevent illness or accidents, avoid unnecessary risks, care and self-medicate for minor ailments and long-term conditions, and maintain health and well-being after an acute illness or discharge from hospital. The results showed that inequalities were related to level of income (Hosseinpoor et al., 2012).

You et al. (2011) conducted a cross-sectional phone survey of approximately 1,100 noninstitutionalized individuals in Hong Kong to determine their knowledge about

using OTC products. The results showed that participants who had no formal education or just a primary education (OR = 3.19; $p < .001$); had a secondary school education (OR = 1.50; $p = .035$); and were > 60 years of age (OR = 1.82; $p = .042$) were more likely to be less knowledgeable of self-medication and the risk factors associated with using OTC medications (You et al., 2011).

OTC Medications and Lack of Medical Supervision

OTC medications can be taken without the advice of pharmacists or doctors. They are commonly available, and their use is perceived as safe (Neafsey & Shellman, 2001). Health care authorities have encouraged the self-care of minor ailments to reduce the cost of medical care (Indermitte, Reber, Beutler, Bruppacher, & Hersberger, 2007), but the lack of supervision might increase the risk of adverse drug effects, including those caused by drug-drug interactions. Furthermore, unless patients receive support or guidance from physicians, their questions about the consumption of OTC medications and dietary supplements will remain unanswered (Haverhals et al., 2011; Hughes et al., 2001).

Consumption of NSAIDs is an important patient safety concern. Self-medication drugs are not required to be monitored systematically and are usually not documented in people's medication histories (Indermitte et al., 2007). The Joint Commission on National Patient Safety (as cited in Kovac et al., 2008) recommended obtaining and keeping a complete and up-to-date list of all patients' medications in an effort to decrease adverse drug events. Despite the national goal of wanting to generate awareness to improve patient care, no data have documented improvements in communication between patients and physicians in regard to the appropriate consumption of NSAIDs. Indermitte et al.

(2007) suggested that because of the increased use of OTC medications, the U.S. federal government should consider initiating a policy to monitors patients' self-medication behaviors to reduce the risk of adverse events that are otherwise preventable. Furthermore, no universal standardized system is in place to measure OTC NSAIDs consumption (Kovac et al., 2008). Because patients do not always consider nonprescription medications to be drugs, they often will not report their nonprescription drug use (i.e., OTC medications) to their physicians. In addition, physicians do not tend to include questions about the consumption of OTC medications during consultations with patients (Hughes et al., 2001).

The quality of the physician-patient relationship and the level of communication between physicians and patients are related to patient outcomes (Ratanawongsa et al., 2008). A higher quality of communication and trust can influence patient satisfaction, compliance, and recall of medical information. Communication also is linked to improved outcomes related to emotional health, functioning symptom resolution, and blood pressure and/or blood sugar control (Ratanawongsa et al., 2008).

Trust refers to the expectation that people will behave in ways that are not harmful (Thom et al., 2011). For example, patients will share information with physicians when there is trust between them. A lack of trust also is likely to affect patients' behavior and health outcomes (Thom et al., 2011). Ratanawongsa et al. (2008) discussed the importance of communication in the physician-patient relationship and its relationship to patient outcomes.

Other factors also can impact self-medication. A qualitative analysis of a series of individual and semistructured group interviews was completed by Haverhals et al. (2011), who studied five concepts related to the challenges of self-medication: reliable medication information, maintenance of autonomy in medication treatment decisions, polymedications, alternative therapies, and the tracking and coordination of health information among multiple providers. Haverhals et al. found that physicians were the least likely to be consulted by patients, even if timely responses were warranted, and that patients believed that physicians were too busy to address their medication information needs. In addition, patients preferred to make independent decisions so that they could remain in control of their treatment regimens. Patients also expressed concern about the consumption of multiple medications, but they had a tendency to remember only prescription medications and frequently not list supplements or nonprescription medications because they did not feel it necessary to discuss them with their physicians (Haverhals et al., 2011). This lack of communication might have been the result of a lack of trust between the patients and their physicians.

Sixty percent to 95% of medical issues are treated initially with self-care, including the use of OTC medications (Amoako, Campbell, & Malone, 2003). Approximately 100,000 OTC drugs are available to consumers, and their use continues to increase (Amoako et al., 2003). Over a 3-month period, Amoako et al. (2003) evaluated the use of nonprescription drugs among an elderly population between the ages of 59 and 91 years who lived in a housing project in North Carolina. A survey with categories involving the consumption of OTC medications focused on the frequency of use, source

of information on OTC adverse drug reactions, demographic factors, perceived health, number of chronic diseases, and other interventions used concurrently with OTC medications was conducted. The results indicated that 90% of the participants used pain medication, 67% used at least one medication for blood pressure, 59% consumed caffeine on a daily basis, and 10% consumed alcohol (Amoako et al., 2003). These percentages showed that physicians should consider the need to improve communication skills with elderly patients to improve the patients' safe use of OTC drugs.

The elderly cohort, that is, people ages 65 years and older, often choose to self-medicate. The Administration of Aging has estimated that by 2030, 72.1 million U.S. citizens will be in this age bracket (as cited in Taylor et al., 2011). According to Amoako et al. (2003), elderly individuals use OTC drugs to self-treat minor illnesses such as fever, runny nose, sore throat, cough, nausea, diarrhea, constipation, indigestion, headache, or muscle or joint pain approximately 69% to 85% of the time. A majority of the elderly population also use prescription and OTC NSAIDs. NSAIDs are the main class of medications used to treat chronic pain (Taylor et al., 2011).

In 1992, Conn (as cited in Amoako et al., 2003) interviewed 185 adults ages 65 years and older to determine their use and management of 16 common OTC medications and found that the respondents used almost twice as many OTC drugs as prescription medications. In 1996, Kriner (as cited in Amoako et al., 2003) conducted a telephone survey of 874 individuals ages 50 years and older to determine their prescription drug use. Sixty-nine percent of the participants ages 65 years and older were taking prescription medications, with an average of 2.4 prescription drugs/participant. More than

half (57%) of the participants indicated that no one reviewed their prescription and OTC medications the last time they received new prescriptions.

Fraenkel, Wittink, Concato, and Fried (2004) conducted a study on prescribed NSAIDs medications. They reported that 54% of the patients who had osteoarthritis were unaware of NSAIDs toxicity and 80% were unaware of cyclooxygenase (COX)-2 toxicity. These results were problematic because of the wide availability of OTC NSAIDs and the lack of patient communication with physicians about their use of OTC NSAIDs.

The American College of Gastroenterology (as cited in Lanza, Chan, & Quigley, 2009) reported that approximately 20% of the respondents in the study did not report their use of NSAIDs to their physicians; 22% did not believe that the medications were important enough to list or discuss; and 30% reported that because they were not prescribed medications, it was unimportant for their physicians to know about them. The responses reflected a common misconception that these medications are insignificant or benign; however, when used on a chronic basis, particularly among the elderly cohort, these medications can lead to serious and potentially fatal adverse events (Okura, Urban, & Mahoney, 2004). Adverse side effects of NSAIDs include gastrointestinal, cardiovascular, renal, and hematological problems (Taylor et al., 2011). Prescribing NSAIDs to elderly patients requires physicians to be knowledgeable and aware of individual patient risk factors, be able to assess the risk-benefit ratio, and take responsibility for educating patients and monitoring the effectiveness and side effects of this class of medications (Taylor et al., 2011).

OTC Medication Consumption and Communication With Physicians

As mentioned previously, patients do not routinely discuss their OTC medication consumption with their own physicians or other physicians. In addition, patients' racial or ethnic backgrounds can affect the quality of patient-physician communication during medical visits (R. Johnson, Roter, Powe, & Cooper, 2004). R. Johnson et al. (2004) used audiotaped interviews and questionnaires to look for any differences in the quality of medical visit communications between African American and European American patients in Baltimore, the District of Columbia, and Virginia. The results showed that physicians were more verbally dominant and less patient centered with African American patients than with European American patients. R. Johnson et al. suggested that this lack of patient-centered communication, including less patient input into the medical dialogue (i.e., building rapport), might be contributing to health care disparities or continuity of care.

However, other studies on patient-physician communication have not focused specifically on the consumption of NSAIDs, an important patient safety concern. The Joint Commission recommended obtaining and keeping up-to-date lists of all patients' medications in an effort to decrease adverse drug events (as cited in Kovac et al., 2008). Maintaining current lists of patients' medications, prescription and OTC, might help to improve communication between patients and physicians about the appropriate consumption of NSAIDs.

Torrible and Hogan (1997) examined the medications of 25 patients ages 75 years and older who lived in a rural area of southern Alberta. They obtained the information

from medical records and in-home interviews. The patients took an average of five or six prescribed medications and 3.5 OTC medications. The results showed that the family physicians and the primary dispensing pharmacists were aware of only some of their patients' medication regimens (Torrible & Hogan, 1997). The researchers also found that these elderly patients often would misinform their health care providers about their use of medications.

Lack of knowledge and poor communication are remediable reasons for the failure to achieve self-care. Before designing interventions to improve self-medication regimens, it is important to characterize self-medicating patterns within the community. Particularly in the elderly population, special attention is warranted because of the increased potential occurrence of adverse events.

It is common for people to choose OTC medications without the supervision of physicians. Self-medication might be an obstacle to patient care because of the lack of communication and safety (You et al., 2011), so it is important to understand why there are variations in the levels of self-care among individuals. The Self-Medicating Scale (SMS), developed and validated by James and French (2008), can be used to describe individuals' self-medication beliefs and how they make decisions about self-treatment as a response to everyday symptoms.

People tend to behave differently when they are ill (Klemenc-Ketis & Kersnik, 2011). Encouraging self-care relies on the careful design of interventions to support positive health-seeking behavior (James & French, 2008). For instance, some people might choose to self-medicate at the first indication of discomfort, whereas other

individuals might choose to self-medicate after symptoms have developed further and they have reached their threshold of pain tolerance (James & French, 2008; Klemenc-Ketis & Kersnik, 2011). As a result, it is important to understand individuals' self-medicating habits. Beliefs about dealing with illness and taking medications can influence health-related behaviors, including adherence to treatment regimens prescribed by physician as well as self-care that includes OTC medication choices (James & French, 2008).

Elderly individuals consume OTC medications for different reasons. For instance, NSAIDs or COX-2 selective inhibitors have become the preferred option to relieve pain and increase mobility (White, 2009). OTC analgesics include acetaminophen and NSAIDs such as ibuprofen, naproxen, and aspirin. NSAIDs, however, do not have a clean profile of side effects, even though many are safe enough to be purchased without prescriptions. This class of medication is the most common cause of reported adverse reactions, including gastrointestinal, cardiovascular, and renal problems (Sulaiman, Seung, & Ismail, 2012).

NSAIDs can cause gastrointestinal complications (Tamer, Moore, Reynolds, & McQuay, 2000), so researchers have tended to focus their attention on these gastrointestinal side effects. For instance, Adams et al. (2011) reported that the rate of death from NSAIDs-related gastrointestinal complications is higher than that from cervical cancer, asthma, or malignant melanoma. They also reported that the incidence of gastrointestinal bleeding among people who are taking NSAIDs is .69%, compared with .002% for those not taking NSAIDs. Approximately 100,000 hospitalizations secondary

to NSAIDs-induced gastrointestinal complications occur annually, and approximately one of every 1,200 people consuming NSAIDs for more than 2 months will die from gastrointestinal complications (Breedveld, 2003). NSAIDs also increase blood pressure, placing people who consume NSAIDs for long periods at increased risk of thrombotic events such as cerebrovascular accidents and myocardial infarction (Mackenzie & MacDonald, 2010).

The Sloan Survey, which was conducted in the United States, found that more than twice as many people used acetaminophen (23%), ibuprofen (17%), or aspirin (17%) than any other OTC medications (as cited in McDonald et al., 2007). Similar results were reported in a survey conducted in Finland (as cited in McDonald et al., 2007), where 27% of the participants reported consuming OTC analgesics a few times each week (as cited in McDonald et al., 2007). The safe and effective use of OTC analgesics can decrease pain and improve functional status, but the unsafe and inappropriate consumption of OTC analgesics can result in serious and sometimes fatal consequences (McDonald et al., 2007).

McDonald et al. (2007) cited the Sloan Survey's findings that 36% of the patients diagnosed with epigastric bleeds did not know that this bleeding is a common adverse event related to the consumption of NSAIDs and had experienced pain before their bleeding. However, only 11.1% of the patients discontinued their NSAIDs consumption. On the other hand, only 15% of the patients with epigastric bleeds who had been informed about adverse events reported experiencing pain before the bleeding, and 67% consequently decreased their NSAIDs consumption (McDonald et al., 2007). Prescribing

NSAIDs or using OTC NSAIDs involves knowing the individual risk factors to patients and assessing the risk-benefit ratio.

Adams et al. (2011) found that patients who had increased their consumption of NSAIDs were at increased risk of adverse events and also had been diagnosed with chronic conditions that contraindicated NSAIDs use. For instance, approximately 75% of the individuals in the study who consumed NSAIDs had one or more medical complications of cardiovascular disease, hypertension, or chronic renal failure. The use of NSAIDs in this patient population was not the result of self-medication OTC NSAIDs consumption, but of the result of treatment regimens directed by physicians that include prescriptions for NSAIDs (Adams et al., 2011).

The incidence of adverse events related to prescribed NSAIDs emphasizes the importance of examining patterns of NSAIDs use by the elderly population. Patients' attitudes and knowledge, as well as their willingness to ask their physicians questions, might have an impact on their levels of NSAIDs use. It is important for physicians to determine whether the use of NSAIDs continues because the users want relief, despite the risk of adverse events, or because they lack awareness of the potential adverse side effects of prescription and OTC NSAIDs.

Timely access to care as well as diagnostic, preventative, and therapeutic services and modalities is not the only measure of the quality of health care received. Patient-centered care and patient-physician communications might be aspects of racial and ethnic disparities. Patient-physician communication, for example, is an integral part of clinical practice. During health care visits with their patients, physicians must make choices about

the appropriate use of words, questions, silences, tone of voice, and facial expressions Because these choices can enhance or detract from the overall delivery of care.

R. Johnson et al. (2004) collected data from 1998 to 2002 from 61 physicians in the District of Columbia and surrounding area to determine whether the quality of medical visits and visit communication was different for African American and European American patients. The results showed that patient engagement and participation rather than overall time spent with the physician could play a role in health care disparities. For instance, R. Johnson et al. reported that 23% of the physicians were more verbally dominant and engaged in 33% less patient-centered communication with African American than with European American patients. In 2002, van Wieringen, Harmsen, and Bruijnzeels noted that in the Netherlands, there was a decreased positive effect of medical visits made by racial or ethnic minority patients than by native-born Dutch patients.

Individuals might benefit from receiving information about prescription or OTC medications that can improve their safe use of OTC analgesics and avoid potential adverse events (McDonald et al., 2007). A pamphlet prepared several years ago by the FDA (as cited in McDonald et al., 2007) provides safety information about taking OTC analgesics. However, the pamphlet does not explain the potential interactions of NSAIDs and antihypertensive medications; the potential interactions of acetaminophen and alcohol; and the fact that taking more than the maximum recommended dose of NSAIDs provides no greater analgesia (i.e., ceiling effects). Perhaps if more information were added to the educational material, it would increase the safe use of OTC analgesics by consumers.

The purpose of the study by McDonald et al. (2007) was to test the effect of adding information to the FDA pamphlet on the safe administration of OTC analgesics. This study was a randomized, double-blind, posttest-only investigation with a sample of 137 adults who evaluated the updated FDA pamphlet, which included the aforementioned additional safety information about OTC analgesics. The results were not positive and indicated that adding additional information about potential NSAIDs interactions with antihypertensive medications, the potential interaction of alcohol and acetaminophen, and NSAIDs ceiling effects did not impact the consumption of OTC analgesics. The results also highlighted that the mode of delivery of educational materials (i.e., written or verbal) can influence the recipients' knowledge and awareness of NSAIDs. It is important that people be educated about the OTC analgesics that they plan to take so that they can make informed decisions about the relative risks and benefits (McDonald et al., 2007).

Roumie and Griffin (2004) found that 33% of the 1,000 adults whom they surveyed took more than the recommended doses of their nonprescription medications because they felt that the extra doses would increase the effectiveness of the medications. Sulaiman et al. (2012) reported that success in patient therapy depends on patients' choices of medication as well as their compliance. Drug information that physicians share with patients should include pharmacological properties, instructions for use, warnings as well as indication (Sulaiman et al., 2012).

Twenty-one percent of the respondents in McDonald et al.'s (2007) study indicated that they would take a second dose before the recommended time, which meant that they were placing themselves at increased risk of adverse drug events. In addition to

the patients in the study who did not follow the recommended dosages, patients with past medical histories or current medical illnesses also were identified as being at increased risk of adverse drug events with certain OTC medications. For example, patients with poor renal function were identified as being at increased risk of kidney damage when taking NSAIDs, which also can interfere with antihypertensive medications by decreasing the effectiveness of the medications and impacting blood pressure levels (McDonald et al., 2007).

McDonald et al.'s (2007) meta-analysis of 45 studies found a significantly increased risk of developing gastrointestinal complications when the participants took NSAIDs for 84 days or more; participants who took naproxen increased their risk of gastrointestinal complications by 1.83 times. In addition, McDonald et al. reported that a randomized-controlled clinical PAIN study conducted in France with 8,677 people compared acetaminophen, aspirin, and ibuprofen use for the frequency of adverse drug events. The results showed that a total of 1,347 (15.6%) of the participants experienced significant adverse events from taking NSAIDs. Aspirin had the highest incidence of adverse events, but the incidence of adverse events was similar for acetaminophen and ibuprofen (McDonald et al., 2007).

The annual report of the American Association of Poison Control Center National Poison Data System (as cited in Hunter, Wood, & Dargan, 2011) indicated that analgesics are the most common category of drug in acute overdose in adult patients (10%) and the second most common in pediatric patients (9%). Acetaminophen consumed independently or as an ingredient in other medications was identified as the most

common analgesic in an acute overdose (42%), with NSAIDs contributing to 33% of reported analgesic acute ingestions. Ibuprofen was the most common NSAIDs taken in overdose (81%), followed by naproxen (11%; as cited in Hunter et al., 2011).

Neafsey et al. (2002) published many studies on the use of OTC NSAIDs. Neafsey et al. found that elderly patients who presented at clinics for blood pressure were at increased risk of adverse drug reactions because of their decisions to self-medicate or because their knowledge of potential interactions from self-medication practices was low. Neafsey et al. also studied the use of a computerized personal education program to educate residents in seniors' centers in rural New England about possible drug interactions when self-dosing with OTC medications and consuming alcohol. The results showed an increase in the treatment group's level of knowledge of potential interactions of prescription medications with OTC medications and alcohol compared to that of the control group (Neafsey et al., 2002).

The results of Neafsey et al.'s (2002) study were not confounded based upon age and level of education, suggesting that this electronic program was effective. Future studies involving the use of this personal education program might be beneficial with individuals of lower education levels to help to remove the barriers of advanced age and limited education in health literacy efforts (Neafsey et al., 2002). Education is a key component in efforts to modify OTC medication practices.

Another study at the Rheumatology Clinic in Northern Malaysia included patients 18 years of age and older (Sulaiman et al., 2012). The purpose of the study was to demonstrate that educating patients about prescription NSAIDs use could result in greater

patient satisfaction. Sulaiman et al. (2012) found that the low SES, education, and literacy levels of some patients were factors affecting the use of prescription medications. The results highlighted the importance of providing guidance and knowledge to patients about the consumption of prescription medications as well as the need to gain a better understanding of the elderly population's levels of consumption of OTC NSAIDs. Drug information that is shared with patients should include pharmacological properties, instructions for use, warnings, and potential contraindications about consumption (Sulaiman et al., 2012).

The results of Neafsey et al.'s (2002) study cannot be generalized to the entire population of older adults because the participants in their study were mostly European American females and the sample was not large enough to compare the effectiveness of race versus gender. The personal education program was being studied on a larger scale in two racially and economically diverse urban communities. The results of Neafsey et al.'s study will help to determine whether educational programs are equally effective with males and females, along with European Americans, African Americans, and English-speaking Latino Americans. The implication for future practice is that the delivery of health information to older adults via computers equipped with touch screens has the potential to revolutionize the delivery of public health education by community nurses and other allied health professionals.

The appropriate consumption of medications may help to decrease the rates of adverse events and premature death (Taylor et al., 2011). In 2001, more than 4 million people had adverse events secondary to taking medications inappropriately (Taylor et al.,

2011). According to reports from the Institute of Medicine (as cited in Taylor et al., 2011), approximately 1.5 million of adverse events can be prevented and that 50% of preventions will happen if physicians change their prescribing regimens and know what other types of medications, including OTC drugs, their patients are taking. Taylor et al. (2011) evaluated 807 NSAIDs users and found that 54% of the participants did not know the side effects associated with this class of medication, 33% believed that prescription NSAIDs are safer, 32% believed that OTC NSAIDs are safer, 20% believed that there is no difference, and 15% did not know. Sixty-percent of the participants, as well as 29% who were exclusive OTC NSAIDs users, were neither aware of nor believed that they were at risk of side effects from consuming NSAIDs.

In addition to the decreased awareness of side effects when taking one of the NSAIDs, patients also were unaware of the side effects of taking multiple NSAIDs or taking NSAIDs for extended periods (Taylor et al., 2011). Taylor et al (2011) studied patients with chronic pain and their knowledge of the risks of taking prescribed NSAIDs and OTC NSAIDs. Forty-nine percent knew that taking multiple NSAIDs increased the risk of side effects, 41% were uncertain, and 10% did not believe that there were any risks. Physicians need to educate their patients in an effort to improve their awareness.

Trelle et al. (2011) completed a meta-analysis of the cardiovascular safety of seven prescription NSAIDs (naproxen, ibuprofen, diclofenac, celecoxib, etoricoxib, rofecoxib, or lumiracoxib) and a placebo. The primary endpoint looked at the rates of myocardial infarction, and the secondary endpoints included stroke death from cardiovascular disease and death from any other cause (Trelle et al., 2011). When

comparing the NSAIDs to a placebo, rofecoxib was associated with the highest risk of myocardial infarction, followed by lumiracoxib. Ibuprofen was associated with the highest risk of stroke, followed by diclofenac. Etoricoxib and diclofenac were associated with the highest risk of cardiovascular death (Trelle et al., 2011).

Data from the Health Improvement Network (nested case-control study) of 8,852 people between the ages of 50 and 84 years were analyzed by Rodriguez, Tacconelli, and Patrignani (2008) to determine whether there was an association between prescription NSAIDs and the risk of nonfatal myocardial infarction. The results showed that the risk of myocardial infarction varied, depending upon the type of NSAIDs consumed and the extent of COX-2 inhibition. For NSAIDs with a degree of COX-2 inhibition < 90%, the RR was 1.18, whereas NSAIDs with a greater COX-2 inhibition had an RR of 1.60. The data also exhibited an increased risk of myocardial infarction, depending upon treatment duration and daily dose (Rodriguez et al., 2008).

Fosbol et al. (2010) looked at the cardiovascular risk of healthy individuals in Denmark who used NSAIDs. This population-based, historic cohort study was conducted to examine specific cardiovascular risk (i.e., morbidity and mortality) in relation to treatment with and patient consumption of NSAIDs. The results showed that NSAIDs have different degrees of risk concerning cardiovascular morbidity and mortality.

According to van Staa, Rietbrock, Setakis, and Leufkens (2008), the longer that patients use NSAIDs, the greater is the risk of myocardial infarction, a risk that continues for years after the cessation of NSAIDs use. This increased risk, even after NSAIDs use has stopped, could be the result of the initiation of alternative medications that could

increase the risk of myocardial infarction (van Staa et al., 2008). There also has been a gap in understanding whether the side effects of NSAIDs might continue for years after therapy has stopped (van Staa et al., 2008). The results of the study were consistent with other epidemiological studies in showing that the relative risk of myocardial infarction was strongly associated with NSAIDs exposure and that the risk was the lowest among patients who used NSAIDs over the short term or intermittently and the highest among patients who consumed NSAIDs over the long term and every day.

Van Staa et al. (2008) also looked at different NSAIDs (diclofenac, ibuprofen, and naproxen) and found that the risk of myocardial infarction was the same for all of them. However, looking back at other observational studies, van Staa et al. found that the relative risk of myocardial infarction based upon the NSAIDs used was 1.40 for diclofenac, 1.07 for ibuprofen, and .97 for naproxen.

International guidelines discourage NSAIDs treatment of patients with established cardiovascular disease; however, if such a treatment regimen cannot be avoided, the duration of NSAIDs use should be as short as possible (Olsen et al., 2011). According to Olsen et al. (2011), only a few researchers have looked at time to event for NSAIDs treatment, and the results have identified an increased risk at the initiation of therapy that continues until the cessation of treatment. Two randomized studies were designed specifically to determine the cardiovascular safety of NSAIDs treatment. Olsen et al. used the Danish National Patient Registry to determine whether the duration of NSAIDs treatment affected the cardiovascular risk in patients after myocardial infarction. The main results showed that the risks of death and death regarding myocardial infarction

were independent of the duration of NSAIDs treatment and that the risk of some NSAIDs became apparent immediately (diclofenac) or early (rofecoxib and ibuprofen) and after onset. The results supported past research indicating that patients with previous myocardial infarction are at increased risk when taking NSAIDs, especially diclofenac and selective COX-2 inhibitors.

NSAIDs help to control inflammation and pain, especially among the elderly population, but they also cause gastrointestinal complications. Atrial fibrillation is a common rhythm disorder among the elderly population (Schmidt, Christiansen, Mehnert, Rothman, & Sorensen, 2011) that is associated with morbidity and mortality. The use of NSAIDs might increase the risk of atrial fibrillation because of adverse renal complications that include fluid retention, electrolyte disturbances, and blood pressure destabilization. Schmidt et al. (2011) used the Danish National Registry of Patients to evaluate atrial fibrillation patients and assess NSAIDs use. The results showed that patients starting treatment with nonaspirin NSAIDs were at more risk than patients not using NSAIDs of atrial fibrillation or flutter. The relative increase was 40% to 70% (the lowest for nonselective NSAIDs and the highest for COX-2 inhibitors) and was the greatest among the elderly population. When physicians are prescribing NSAIDs, they need to identify atrial fibrillation or flutter as potential cardiovascular risks (Schmidt et al., 2011).

Theoretical Framework

Preventative health care behavior is associated with an expectancy-value approach. Expectancy refers to individuals' beliefs about how well they can perform

tasks or activities, and value refers to incentives or reasons for performing tasks or activities (Ng, Kankanhalli, & Xu, 2009). Attitudes toward specific behaviors are a function of individuals' perceived likelihood of outcomes associated with the behaviors and the expected values or evaluations of those outcomes (Ng et al., 2009). The expectancy-value model is the building block of the HBM, which posits that individuals' behaviors can be explained by attitudes and beliefs (Boskey, 2008), that is, the values that they place on particular goals and the likelihood that given actions will achieve those goals (Galvin, 1992).

The HBM is a social cognition framework used by researchers to study health behaviors (Hochbaum, 1958; Shanks, 2009; Thompson & Caltabiano, 2010). This model includes elements of individuals' perceptions or beliefs influencing whether or not they will initiate health actions to avoid or prevent disease or illness (Hochbaum, 1958; Shanks, 2009; Thompson & Caltabiano, 2010). The HBM takes into account different perceptions that include perceived susceptibility of acquiring a health condition, perceived severity of the condition and its consequences, perceived barriers to engaging in the recommended behavior, perceived benefits of engaging in the recommended behavior, and perceived costs of engaging in the recommended behavior (Shanks, 2009; Thompson & Caltabiano, 2010). The HBM assumes that people are more likely to engage in disease prevention behaviors if they perceive that they are highly susceptible to the disease, the disease is serious, the behaviors are beneficial, the behaviors have few barriers, and they are cued to perform the behaviors (Chen et al., 2011; Guvenc, Akyuz, & Acikel, 2010).

To make informed choices, patients must be knowledgeable of the benefits and risks of medication. Knowing the safety aspects of medicine use is important to prevent poor health outcomes. I chose the HBM as the framework for this study because previous use of this model has shown it to be effective in identifying individuals' readiness to engage in health behaviors initiated by a perceived threat of disease, the perception of susceptibility to disease, perceived potential severity, and perceived benefits and barriers (Glanz et al., 2002; Hochbaum, 1958). I also examined differences in perceived severity or adverse events resulting from OTC NSAIDs use and perceived susceptibility of adverse events resulting from consumption.

Research based upon the HBM has typically considered the effect of demographic variables, personality, perceived efficacy, motivation, perceived threat, and external influences on the beliefs that guide individuals to make the right choices. For example, understanding individuals' beliefs about their medical conditions and treatment regimens can be an opportunity to impact their adherence to drug treatment (Mann, Ponieman, Leventhal, & Halm, 2009). In a meta-analysis of 26 studies, Mann et al. (2009) found that psychological factors such as emotional stability, internal and external motivations, perceived benefit, and supportive structure are associated with better adherence to treatment medications. One incentive for individuals to participate in behavioral changes is the level of importance that they place on such modifying factors as body symptoms, media attention, illness of another person, postcard reminder of an appointment, or advice from others (Shanks, 2009). Additional modifying factors that can trigger behavioral changes include demographic variables (e.g., age, race, gender, or SES);

sociopsychological variables (e.g., social support, depression, or anxiety); and structural variables (e.g., knowledge about a disease or prior experience with the disease; Shanks, 2009).

The theoretical foundation of the HBM suggests that people will not engage in behavioral changes unless they perceive that they are at risk of a disease or an illness and need to act (Hazaveshei, Taghdisi, & Saidi, 2007). The HBM was the theoretical framework of this study, which was conducted in an effort to help to prevent adverse events resulting from the inappropriate consumption of OTC NSAIDs. The HBM has three components: individual perceptions, modifying factors, and variables likely to affect initiating action. Individual perceptions include perceived susceptibility, perceived seriousness or severity, and perceived threat. Modifying factors are the factors that modify perceptions of a health action and encompass demographic variables (e.g., age, gender, etc.); sociopsychological variables, that is, the influence of peers or other reference groups that encourage preventive health behaviors, despite low motivation; structural variables, or knowledge of the target disease and prior contact with it; and cues to action, either internal or external (Galvin, 1992; Thompson & Caltabiano, 2010). The last component is likelihood to take action, which is the probability of taking the recommended preventive health actions, depending on the perceived benefits of the actions minus the perceived barriers, impediments, or obstacles to adopting the actions (Galvin, 1992; Thompson & Caltabiano, 2010).

The HBM posits that readiness to engage in health behaviors is initiated by a perceived threat of a disease; perception of susceptibility to the disease; and the potential

severity, benefits, and barriers (Galvin, 1992; Thompson & Caltabiano, 2010). Perceived susceptibility refers to the subjective perception of the likelihood of experiencing health complication/s or conditions (Shanks, 2009). Perceived severity represents the associated feelings about the seriousness in terms of health (i.e., disability or death) and social consequences (i.e., job or family; Shanks, 2009). The level of perceived threat also might be based upon other variables, including knowledge. Perceived benefits refer to beliefs about the effectiveness of particular actions in decreasing threats to health (Shanks, 2009).

According to the HBM, perceiving health complications or conditions as threats drive individuals to make behavioral changes; however, specific preventative behavioral changes might depend on the effectiveness of the tools available that can help to decrease such threats. Perceived barriers are the potentially negative obstacles that might discourage behavioral changes. These barriers can include behaviors that are time-consuming, inconvenient, or expensive endeavors.

The HBM shows that individuals will weigh the effectiveness of behavioral change against the barriers before engaging in the behaviors. When the benefits of behavioral change outweigh the barriers, individuals will be motivated to engage in actions that will demonstrate change (Thompson & Caltabiano, 2010). In addition, modifying factors might influence individuals to engage in behavioral changes that include cues to action and self-efficacy (Noroozi et al., 2011).

Self-efficacy refers to the confidence to participate in behavioral change (Noroozi et al., 2011). Increasing individuals' awareness of their risk of a disease or a condition

also might influence their readiness for change (Lopez & McMahan, 2007). Overall, the HBM suggests that people will be more motivated to make healthier choices if they believe that they are susceptible to particular negative health outcomes (Carpenter, 2010). People will not act to prevent negative health outcomes if they believe that the chances of their being affected by such outcomes are minimal (Carpenter, 2010). The stronger that people's perceptions of the severity of negative health outcomes are, the more motivated they become to act upon behavioral changes to avoid such outcomes. However, if they perceive that the health outcomes will not have an impact on their lives, they will be less likely to embrace any changes (Carpenter, 2010).

The HBM is appropriate for different populations and a variety of conditions or illnesses. The HBM helps researchers to understand behaviors and to answer questions about health conditions and illnesses concerning the intent to change behaviors. In the current study, changing individuals' behaviors toward the consumption of OTC NSAIDs was considered important and beneficial to their health status and quality of life. This behavioral change needs to be viewed as a positive health behavior. When developing and implementing interventions to facilitate this behavioral change, it is important to recognize and identify individuals' beliefs and the barriers that they will face when making such a change. I used the HBM to identify individuals' decisions to adopt behavioral change in regard to excessive consumption of OTC NSAIDs in response to the threat of illness, that is, the participants' perceptions of illness threat and evaluation of behaviors to resolve this threat.

Because perceived susceptibility associated with specific behaviors can vary among a population, it is necessary to understand the perceived susceptibility to and seriousness of adverse events related to an increased consumption of OTC NSAIDs because of the increased risk of uncontrolled blood pressure, gastrointestinal complications, and kidney failure. Perceived susceptibility focuses on individuals' knowledge and belief of the ways that behavioral change can impact their lives. In the HBM, perceived benefits refer to individuals' beliefs about the relative effectiveness of actions to reduce the threat of disease. Beliefs about the availability and effectiveness of various courses of actions, not the objective facts about the benefits, determine health behaviors. I focused on perceived benefits regarding on how elderly individuals (i.e., ≥ 65 years) will adapt to new healthy behaviors and how this belief will help to decrease the likelihood of preventable adverse events.

The perceived severity of an illness initiates the need for individuals to make changes to their lifestyles; however, people often are faced with barriers to make changes that can include a lack of education or knowledge, lack of awareness, and lack of communication with their physicians. Although people might believe that given actions are effective in reducing threats to their health, they also might find these actions inconvenient or unpleasant. Health care actions might not occur unless precipitating actions (i.e., cues to action) set the process in motion. Examples of cues to action include internal perceptions of symptoms, impact of the media, knowledge of others who might be experiencing similar diseases, or reminders by physicians. The results of this study

might lead to an increase in individuals' health consciousness and willingness to engage in more preventative health care behaviors.

Summary

Included in this chapter was a discussion of self-care, the engagement in activities that are learned and are meant to promote healthy functioning based upon beliefs; health status; and sociodemographic characteristics (e.g., age, gender, culture, education and marital status) and traits (Fredericks & Sidani, 2012). As a part of self-care regimens, some individuals choose to self-medicate to treat self-recognized illnesses or symptoms. Afolabi et al. (2012) estimated that approximately 50% to 75% of health care is associated with self-medication. People who choose to self-medicate must be sure that the medication is appropriate for their chronic or recurrent condition and has proven characteristics of safety, quality, and efficacy (WHO, 1998).

Globally, people regularly consume OTC NSAIDs, medications that are available to consumers without physicians' prescriptions. Individuals who consume these medications frequently or chronically are at increased risk of adverse events that might be the result of a lack of supervision that can lead to inappropriate dosing regimens, increased consumption rates, and drug-drug interactions. Because people might not be aware of the risk of misusing OTC NSAIDs, the risk to patient safety has become a concern. Lack of knowledge of potential side effects, along with variances in self-medication, can be prevented. Disseminating information through health care professionals by opening the lines of communication between patients and physicians

might help to decrease adverse events and reveal more appropriate and effective ways to influence attitudes and behaviors.

Included in Chapter 3 is a description of the research design used to study the awareness of the elderly population of the risks associated with OTC NSAIDs consumption. Also presented are descriptions of the sampling procedures, eligibility criteria, instrumentation, data analysis, and protection of human participants.

Chapter 3: Methodology

The main purpose of the study was to examine the association between the use of OTC NSAIDs by elderly individuals and their awareness of the risks associated with such use. The study also was conducted to assess the participants' awareness of the risk of (a) adverse events associated with OTC NSAIDs use and OTC NSAIDs consumption, (b) adverse effects of OTC NSAIDs related to sociodemographic characteristics, and (c) adverse events and patient-physician levels of communication.

The study was guided by three research questions and their hypotheses:

1. To what extent does the awareness of the risk of adverse events associated with OTC NSAIDs use vary by sociodemographic characteristics among the elderly (SES, race/ethnicity, gender, and education)?

H_{01}: There is no significant difference between awareness of the risk of adverse events associated with OTC NSAIDs use and sociodemographic characteristics among the elderly population.

H_{a1}: There is a significant difference between awareness of the risk of adverse events associated with OTC NSAIDs use and sociodemographic characteristics among the elderly population.

2. To what extent does awareness of the risk of adverse events associated with OTC NSAIDs consumption vary by rates of OTC NSAIDs consumption among the elderly population?

H_{02}: There is no significant difference between awareness of the risk of adverse events associated with OTC NSAIDs consumption among the elderly population.

H_{a2}: There is a significant difference between awareness of the risk of adverse events associated with OTC NSAIDs consumption among the elderly population.

3. To what extent are levels of awareness of adverse events associated with OTC NSAIDs consumption and levels of communication with their physicians among the elderly population?

H_{03}: There is no significant difference between awareness of adverse events associated with OTC NSAIDs consumption and the level of communication with physicians among the elderly population.

H_{a3}: There is a significant difference between awareness of adverse events associated with OTC NSAIDs consumption and the level of communication with physicians among the elderly population.

The results might help to fill the gap in the literature regarding the elderly population's awareness of adverse events associated with the use of OTC NSAIDs. This chapter includes a discussion of the research design, instrumentation, sampling method, inclusion criteria, data analysis, and ethical considerations.

Research Design

I conducted a quantitative study with a cross-sectional design to gather data from a sample of elderly individuals in a metropolitan area in the Midwestern United States.

The data were collected from self-administered questionnaires (paper-and-pencil style) regarding medication use; attitudes and beliefs about the use of OTC NSAIDs; communication with health care providers; and sociodemographic characteristics (gender, race, SES, level of education, marital status, and living arrangements). A cross-sectional study design was appropriate for this study because all of the data on each of the independent and dependent variables were collected at one time. The paper-and-pencil style of questionnaire also was an easy and cost-effective way to collect the data. The information gained by using a cross-sectional study design helped me to assess the health needs of the elderly population, which will provide the medical community with information to consider developing and implementing educational programs as well as allocate health resources.

Sample Selection

Purposive sampling was used to select the participants. Purposive samples are a nonrepresentative subset of the larger target population and depend upon the judgment of researchers in regard to their selection (Gregg, 2008; Issel, 2009). When using this type of sampling method, the focus is on a particular group, and predefined criteria determine the location of data collection and the number of participants to be recruited (Crosby, DiClemente, & Salazar, 2006; Gregg, 2008). The sample comprised elderly residents ages 65 years and older at the time of the study from a metropolitan area in the Midwestern United States. Exclusion criteria included being under the age of 65 years at the time of the study and not being able to answer the survey because of psychiatric, medical, or traumatic illness, or language barriers.

Participant recruitment occurred at two senior citizen community centers in the metropolitan area. Memberships at both centers comprise diverse populations. The centers provide appropriate quality recreational and nutritional services to the elderly population within their communities. Both centers gave me permission to collect data.

Sample Size

To determine the sample size needed to answer Research Question 1, I used an a priori sample size calculation for a multiple regression model, G*Power 3.1 software program (Faul, Erdfelder, Buchner, & Lang, 2009). Using 10 independent variables (age, sex, ethnicity, marital status, education level, SES, living arrangements, status of having a physician, consumption of OTC NSAIDs, and communication) based upon a medium effect size ($f^2 = .15$) and an alpha level of .05, the sample size required to achieve sufficient power (.80) was 118 respondents. A limited number of quantitative studies have examined the variables of interest among this population, so precise estimates of effect size could not be used. I selected the aforementioned parameters based upon the expectations of a medium effect and the need to reduce a Type I error.

Recruitment Strategy

As mentioned previously, the participants were recruited from senior citizen community centers in a metropolitan area in the Midwestern United States. Once approval was obtained from Walden University's Institutional Review Board (IRB approval #10-18-13-0169502), I worked with both centers to schedule recruitment dates and location. Once the dates were established, I posted an announcement in the newsletter for each community center indicating the date and location of the recruitment

process. The announcement also included a brief description of the study. On the recruitment date, I sat at a table and provided copies of the survey to interested individuals for them to complete.

Instrumentation

To understand the participants' levels of awareness and knowledge of the consumption of OTC NSAIDs, I asked the participants to complete a paper-and-pencil survey that was a composite of two validated instruments, the Perceived Efficacy in Patient-Physician Interaction Questionnaire (Maly et al., 1998) and the OTC Pain Reliever Survey (Cham et al., 2002). Permission to use these instruments was granted (see Appendix B).

Perceived Efficacy in Patient-Physician Interaction Questionnaire. This instrument assesses patient-physician communication using a 10-point Likert scale ranging from 1 (*no confidence*) to 10 (*very confident*). The scores range from a minimum of 10 to a maximum of 100, the highest patient-perceived efficacy (Maly et al., 1998). The survey held 10 questions to determine levels of patient-physician communication related to understanding the information provided to patients, communicating information from patient to physician, and patients being able to have their physicians address and act on their medical issues (Maly et al., 1998). Each question began with the wording, "How confident are you in your ability to …?" (Maly et al., 1998). Although there have been no published estimates of reliability and validity of the tool, Maly stated that "its reliability in repeated studies since its original publication has demonstrated Cronbach's alphas in

excess of .90 consistently and its construct validity has remained solid" (personal communication, April 16, 2003).

OTC Pain Reliever Survey. This instrument is used to assess the use of OTC medications. Components of the instrument facilitated the collection of demographic information as well as additional health information in the current study to assess how these variables might have impacted the participants' awareness of the consumption of OTC NSAIDs. Responses to the survey were dichotomized to simplify the instrument. There have been no additional publications using Cham et al.'s (2002) questionnaire to demonstrate the validity and reliability of the instrument.

Pilot Test

The questionnaire used to collect the data was a combination of the two aforementioned survey instruments. The tool was precise and comprehensive. Prior to administering the survey, I pilot tested it with 12 participants who were not included in the full study to assess its reliability and validity. The results were then analyzed for reliability and validity. I revised the final instrument as needed based upon the results of the pilot test.

Data Collection

I introduced myself to potential participants as they voluntarily approached the table at each community center and then explained the objective, methods, and design of the study to them. Potential participants were screened to determine their eligibility to join the study. Individuals not eligible to participate received an explanation for that determination. Eligible participants received information regarding confidentiality and

voluntarily signed the informed consent form before receiving the packet, which included a cover letter and the questionnaire. This way, I could retain the consent forms and surveys separately. The procedure was the same at both senior citizen community centers: The participants completed the self-administered survey on site at both community centers, and I was present to answer questions or provide assistance. The term *Caucasian* was used to reflect the wording in the survey. The participants did not receive any compensation for being in the study.

Data Analysis

I analyzed the data using SPSS. The statistical analysis of the data helped to answer the three research questions. Table 1 presents the research questions, the relevant survey items to address each question, and the statistical test used. The variables that were used in these multiple regression calculations were age, sex, ethnicity, marital status, level of education, living arrangements, SES (level of income), presence of primary care physician, level of physician-patient communication, and consumption of OTC NSAIDs.

Table 1

Research Questions and Statistical Test

Research questions	Survey items	Statistical test
1. To what extent does the awareness of the risk of adverse events associated with OTC NSAIDs use vary by sociodemographic characteristics among the elderly (SES, race/ethnicity, gender, and education)?	Awareness scale (Items 14-22) Sociodemographic (Items 1-8)	Multiple linear regression
2. To what extent does awareness of the risk of adverse events associated with OTC NSAIDs consumption vary by rates of OTC NSAIDs consumption among the elderly population?	Awareness scale (Items 14-22) Rate of consumption (Items 9-13)	Multiple linear regression
3. To what extent are levels of awareness of adverse events associated with OTC NSAIDs consumption and levels of communication with their physicians among the elderly population?	Awareness scale (Items 14-22) Communication score (Items 23-32)	Multiple linear regression

Protection of Participants' Rights

I adhered to Walden University's IRB guidelines to ensure the confidentiality and privacy of all information, as well as the participants' individual rights. As mentioned previously, no data were collected prior to receiving approval from Walden University's IRB. Participants received and signed the informed consent prior to completing the questionnaire. The informed consent also included information about the purpose and benefits of the study to the elderly community. No identifying information was collected, and the participants were advised that they had the right to withdraw from the study at any time. The responses were anonymous, and I stored the survey and the consent forms separately. I kept all data in a locked and secure location accessible to no one else other than myself. The questionnaire did not pose any risk of harm to anyone who voluntarily chose to participate in the study.

Summary

Included in Chapter 3 was an explanation of the cross-sectional study design used to conduct the research. This chapter also provided information about the research design, sampling plan, recruitment strategy, and data collection and data analysis procedures. The chapter concluded with a summary of the ethical considerations relevant to the study. Chapter 4 explains the results of the data collection and analysis processes.

Chapter 4: Results

The purpose of this study was to determine (a) whether patients are aware of the risks associated with the consumption of OTC NSAIDs, and (b) whether there are differences in awareness based upon specific demographic characteristics. In addition, the study sought to identify the extent to which patient-physician communication levels influence patients' awareness of adverse events. Responses from 124 participants were collected for this study. This chapter explains the results gleaned from the data collection and analysis. Study participant demographic characteristics and an assessment of the research questions also are presented.

As mentioned in Chapter 3, I conducted a pilot study to ensure that the survey comprised a combination of two validated instruments. Prior to administration of the full survey, I had 12 participants assess the instrument to assess its reliability and validity. The results were analyzed for reliability and validity. The final instrument did not need to be revised based upon the results of the pilot test. Table 2 displays the psychometric characteristics for the three summated scale scores using the pilot study data ($N = 12$). Cronbach's alpha reliability coefficients were as follows: communication ($\alpha = .89$), awareness ($\alpha = .74$), and consumption ($\alpha = .97$). All three scales had adequate levels of internal reliability.

Table 2

Psychometric Characteristics for the Summated Scale Scores From Pilot Study

Scale score	No. of items	*M*	*SD*	Low	High	α
Communication	10	8.28	1.87	4.20	10.00	.89
Awareness	7	3.33	2.06	0.00	6.00	.74
Consumption	4	0.00	0.95	-1.03	1.50	.97

Sample Demographics

Ages of the respondents ranged from 65 to 97 years (M = 76.1, SD = 7.52). About three quarters of the participants (n = 94, 75.8%) were female, and almost all (n = 120, 96.8%) were Caucasian. About one third (n = 43, 34.7%) of the participants were married, and another 46.8% (n = 58) reported being widowed. Sixty-one percent (n = 75) of the participants had attended at least some college courses, with 25.0% (n = 31) having earned a college degree. Almost all (n = 122, 98.4%) of the participants had a primary care doctor, and about half (n = 64, 51.6%) lived alone. For the 101 participants who answered the income question, 86.1% (n = 87) reported an annual income of less than $50,000. Table 3 displays the frequency counts for the selected variables.

Table 3

Frequency Counts of Selected Variables Associated With NSAIDs Use

Variable	Category	Frequency	%
Age range[a]			
	65-69	25	20.2
	70-79	61	49.2
	80- 89	34	27.4
	90-97	4	3.2
Gender			
	Male	30	24.2
	Female	94	75.8
Race/Ethnicity			
	Caucasian/White	120	96.8
	Other	4	3.2
Marital status			
	Married	43	34.7
	Widowed	58	46.8
	Single	7	5.6
	Divorced/Separated	16	12.9
Education			
	Less than high school	8	6.5
	High school graduate	41	33.1
	Some college	44	35.5
	College graduate	16	12.9
	Graduate degree	15	12.1

Table 3 Cont'd

Variable	Category	Frequency	%
Primary care doctor			
	No	2	1.6
	Yes	122	98.4
Live alone			
	No	60	48.4
	Yes	64	51.6
Income (*n* = 101)			
	< $25,000	47	46.5
	$25,000 - $50,000	40	39.6
	$50,000 - $100,000	12	11.9
	> $100,000	2	2.0
Take NSAIDS			
	No	29	23.4
	Yes	95	76.6

Note. [a]Age: *M* = 76.10, *SD* = 7.52
N = 124

Table 4 displays the frequency counts for the type of OTC NSAIDs categories used sorted by the highest frequency. The results showed that almost 77% of the sample reported taking NSAIDs. The most commonly used NSAIDs were aspirin (*n* = 46, 37.1%) and acetaminophen (35.5%).

Table 4

OTC NSAIDs Categories Used by Highest Frequency

NSAIDs category	Frequency (*N* = 124)	%
Aspirin	46	37.1
Acetaminophen	44	35.5
Ibuprofen	32	25.8
Naproxen	25	20.2
Other NSAIDs	2	1.6

Note. Multiple options were available on the survey. Overall, 95 respondents (76.6%) reported taking NSAIDs.

Table 5 displays the frequency of NSAIDS use. The number of NSAIDs brands used ranged from 0 (*n* = 28, 22.6%) to four or more (*n* = 10, 8.1%; *Mdn* = 1). The number of NSAID brands included the generic name as well as the brand name for the same

active ingredient. It did not account for different labeling of the different products, as was reflected in the questionnaire. The number of NSAIDs days per month ranged from 0 (n = 35, 28.2%) to 22 to 30 (n = 34, 27.4%; *Mdn* = 4). The number of NSAIDs treatments per day ranged from 0 (n = 37, 29.8%) to three or more (n = 11, 8.9%; *Mdn* = 1). For the 88 respondents who answered the question pertaining to NSAIDs history, 73.9% (n = 65) reported using the drugs for longer than 6 months.

Table 5

Frequency Count of NSAIDs Consumption

Variable	Category	Frequency (N = 124)	%
No. of NSAIDs brands[a]			
	0	28	22.6
	1	50	40.2
	2	26	21.0
	3	10	8.1
	4 or more	10	8.1
NSAIDs days/month[b]			
	0	35	28.2
	1-7	46	37.2
	8-21	9	7.2
	22-30	34	27.4
NSAIDs treatments/day[c]			
	0	37	29.8
	1	50	40.3
	2	26	21.0
	3 or more	11	8.9
NSAIDs history (n = 88)			
	1 week	4	4.5
	2-3 weeks	3	3.4
	1 month	4	4.5
	2-3 months	7	8.0
	4-6 months	5	5.7
	> 6 months	65	73.9
NSAIDs categories used[d]	0	30	24.2
	1	56	45.2
	2	24	19.4
	3 or 4	14	11.3

Note. [a]Brands: *Mdn* = 1
[b]Days: *Mdn* = 4
[c]Treatments/day: *Mdn* = 1
[d]Categories: *M* = 1.20, *SD* = 0.99

Table 6 displays the frequency counts for the awareness of adverse events sorted by the highest frequency. The most frequently endorsed awareness items were possible toxic interactions (n = 101, 81.5%) and gastrointestinal irritation (n = 99, 79.8%). The least endorsed awareness items were having personally experienced side effects (n = 21, 16.9%) and awareness of the potential for an asthma attack (25.0%). An individual might have been aware of an adverse event because of personal experience or learning through others.

Table 6

Frequency Count of Awareness of Adverse Events Associated With NSAIDs Use

Awareness item	*n*	%
Possible toxic interactions	101	81.5
Gastrointestinal irritation	99	79.8
Discuss with doctor	93	75.0
Kidney toxicity	81	65.3
Liver damage	79	63.7
Asthma attack	31	25.0
Experienced side effects	21	16.9

Note. N = 124

Table 7 displays the descriptive statistics from the Perceived Efficacy in Patient-Physician Interaction Questionnaire (Maly et al., 1998) items sorted by the highest mean. These ratings were made based upon an 11-point Likert scale ranging from 0 (*not confident at all*) to 10 (*extremely confident*). The highest rated items (most confidence) were for Item 27, "Get a doctor to take your chief health concern seriously" (M = 8.27), and Item 31, "Ask your doctor for more information if you do not understand what he/she said" (M = 8.23). The lowest rated items (least confidence) were for Item 23, "Know what questions to ask your doctor" (M = 7.44), and Item 24, "Get a doctor to answer all of your questions" (M = 7.67).

Table 7

Descriptive Statistics for Level of Communication Items Sorted by Highest Mean

Communication item	*M*	*SD*
27. Get a doctor to take your chief health concern seriously	8.27	2.63
31. Ask your doctor for more information if you do not understand what he/she said	8.23	2.61
30. Explain your chief health concern to a doctor	8.23	2.49
25. Ask doctor questions about your chief health concern	8.21	2.62
28. Understand what a doctor tells you	8.05	2.56
29. Get a doctor to do something about your chief health concern	7.97	2.82
22. Get a doctor to pay attention to what you have to say	7.88	2.89
26. Make the most of your visit with your doctor	7.86	2.87
24. Get a doctor to answer all of your questions	7.67	3.00
23. Know what questions to ask your doctor	7.44	2.80

Note. $N = 124$

Table 8 displays the psychometric characteristics for the three summated scale scores. Cronbach's alpha reliability coefficients were as follows: communication ($\alpha = .97$); awareness ($\alpha = .67$); and consumption ($\alpha = .76$). All three scales had adequate levels of internal reliability.

Table 8

Psychometric Characteristics for the Summated Scale Scores

Scale score	No. of items	*M*	*SD*	Low	High	α
Communication	10	7.98	2.44	0.00	10.00	.97
Awareness	7	4.07	1.75	0.00	7.00	.67
Consumption	4	0.00	0.76	-1.23	2.15	.76

Note. $N = 124$

Answering the Research Questions

Awareness of Risk and Sociodemographic Characteristics

RQ1: To what extent does the awareness of the risk of adverse events associated with OTC NSAIDs use vary by sociodemographic characteristics among the elderly (SES, race/ethnicity, gender, and education)?

H_{01}: There is no significant difference between awareness of the risk of adverse events associated with OTC NSAIDs use and sociodemographic characteristics among the elderly population.

This question was examined, and the responses were assessed using the Pearson product-moment correlations and stepwise multiple linear regression. The results of these analyses indicated that none of the seven sociodemographic variables was related to the respondents' awareness scores. As a subsequent analytical method, I used a stepwise multiple regression model to predict the respondents' awareness scores based upon the seven sociodemographic variables. Given that none of the seven sociodemographic variables was significantly related to the respondents' awareness scores, the stepwise multiple regression model contained no independent variables (i.e., no table shown). This combination of findings supported the retention of Null Hypothesis 1 (see Table 9).

Table 9

Pearson Correlations for the Awareness Scale With the Sociodemographic Variables

Sociodemographic variables	Awareness
Age	-.12
Gender[a]	-.07
Married[b]	.05
Education	.03
Has a primary care doctor[b]	.01
Lives alone[b]	.01
Income (n = 101)	.18

Note. [a]Gender: 1 = Male 2 = Female
[b]Coding: 0 = No 1 = Yes (N = 124)
[*]$p < .05$
$p < .01$
$p < .005$
$p < .001$

Table 10 displays the results of the standard multiple regression model predicting awareness based upon the eight sociodemographic variables. The overall model was not significant (p = .52) and accounted for 6.3% of the variance in the respondents' awareness scores. Inspection of the beta weights found none to be significantly related to the awareness scores.

Table 10

Standard Multiple Linear Regression Model Predicting Awareness Level Based Upon Sociodemographic Variables

Variable	*B*	*SE*	β	*p*
Intercept	5.35	2.69		.05
Age	-0.04	0.02	-.16	.14
Gender[a]	-0.23	0.42	-.06	.58
Married[b]	-0.22	0.61	-.06	.72
Education	-0.02	0.17	-.01	.92
Has a primary care doctor[b]	1.25	1.83	.07	.50
Lives alone[b]	0.20	0.53	.06	.70
Income	0.41	0.28	.18	.15

Note. Full model: $F(8, 115) = 0.89$, $p = .52$, $R^2 = .063$
[a]Gender: 1 = Male 2 = Female
[b]Coding: 0 = No 1 = Yes
$N = 124$

Risk and Consumption

RQ2: To what extent does awareness of the risk of adverse events associated with OTC NSAIDs consumption vary by rates of OTC NSAIDs consumption among the elderly population?

H_{02}: There is no significant difference between awareness of the risk of adverse events associated with OTC NSAIDs consumption among the elderly population.

This question was answered using Pearson product-moment correlations and stepwise multiple linear regression. Table 11 displays the Pearson correlations between

the NSAIDs category variables and the awareness scores. None of the six correlations was significant at the $p < .05$ level. As a subsequent analytical method, I used a stepwise multiple regression model to predict the respondents' awareness scores based upon the 17 consumption variables. Given that none of the 17 consumption variables was significantly related to the respondents' awareness scores, the stepwise multiple regression model contained no independent variables (no table shown). This combination of findings supported the retention of Null Hypothesis 2.

Table 11

Pearson Correlations Between NSAID Category Variables and Awareness

NSAIDs category variables	Awareness
Aspirin	.12
Acetaminophen	.16
Naproxen	.01
Ibuprofen	-.09
Other NSAIDs[a]	-.12
Total categories of NSAIDs used	.09

Note. $p < .05$
$N = 124$

Awareness and Communication

RQ3: To what extent are levels of awareness of adverse events associated with OTC NSAIDs consumption and levels of communication with their physicians among the elderly population?

H_{03}: There is no significant difference between awareness of adverse events associated with OTC NSAIDs consumption and the level of communication with physicians among the elderly population.

This question was answered using Pearson product-moment correlations and stepwise multiple linear regression. Inspection of Table 12 found all 11 communication

variables associated with the respondents' awareness scores. The two strongest correlations were for Item 22, "Get a doctor to pay attention to what you have to say" ($r = .31$, $p < .001$), and Item 23, "Know what questions to ask your doctor" ($r = .30$, $p < .001$).

Table 12

Pearson Correlations for Awareness Scale With Communication Variables

Communication variable	Awareness	
Communication total score	.29	****
22. Get a doctor to pay attention to what you have to say	.31	****
23. Know what questions to ask your doctor	.30	****
24. Get a doctor to answer all of your questions	.28	***
25. Ask doctor questions about your chief health concern	.22	*
26. Make the most of your visit with your doctor	.26	***
27. Get a doctor to take your chief health concern seriously	.22	**
28. Understand what a doctor tells you	.27	***
29. Get a doctor to do something about your chief health concern	.25	***
30. Explain your chief health concern to a doctor	.23	**
31. Ask your doctor for more information if you do not understand what he/she said	.28	***

Note. *$p < .05$
**$p < .01$
***$p < .005$
****$p < .001$

As a subsequent step, I used a stepwise multiple regression model to predict the respondents' awareness scores based on the 11 communication variables (total communication score + 10 individual communication items). The final 1-variable model was significant ($p = .001$) and accounted for 9.5% of the variance in the respondents' awareness levels. Table 13 shows that awareness level was positively correlated with Item 22, "Get a doctor to pay attention to what you have to say" ($\beta = .31$, $p = .001$). This combination of findings (see Tables 11 & 12) supported the rejection of Null Hypothesis 3.

Table 13

Stepwise Multiple Linear Regression Model Predicting Awareness Level Based Upon Selected Variables

Variable	*B*	*SE*	β	*p*
Intercept	2.60	0.44		.001
22. Get a doctor to pay attention to what you have to say	0.19	0.05	.31	.001

Note. Full model: F (1, 122) = 12.87, p = .001 R^2 = .095
Candidate variables = 10
N = 124

Summary

I conducted this study to determine whether elderly patients are aware of the risks associated with the consumption of OTC NSAIDs. The results, which were based upon a cross-sectional survey of 124 participants, showed that the participants' awareness of adverse events associated with NSAIDs use was not associated with the sociodemographic variables, so Null Hypothesis 1 was supported. The results also showed that the participants' awareness of the risks was not related to their rates of consumption, so Null Hypothesis 2 was also retained. In addition, the results showed that awareness was related to patient-physician communication, so Alternative Hypothesis 3 was supported. In the final chapter, these findings are compared to results in the literature, conclusions and implications are drawn, and recommendations are offered.

Chapter 5: Discussions

Introduction

The purpose of this study was to examine the association between the use of OTC NSAIDS to self-medicate by individuals in the elderly population and their awareness of the risks associated with NSAIDS use. The goals of the study were to assess (a) whether there is an association between awareness of risks of adverse events associated with OTC NSAIDS use and OTC NSAIDS consumption, (b) whether this awareness of the risk of the adverse effects of OTC NSAIDS varies by sociodemographic characteristics, and (c) whether awareness of the risk of adverse events is associated with the level and type of communication between patients and physicians. I collected the data from a sample of 124 elderly individuals in a metropolitan area in the Midwestern United States from senior citizen community centers. Included in Chapter 5 are my interpretation of the results based upon the current literature and theoretical framework and an explanation regarding the ways in which these findings can provide valuable information on OTC NSAIDs as well as recommendations for future research.

I used a quantitative, cross-sectional design to conduct a study regarding the participants' medication use, attitudes and beliefs about the use of OTC NSAIDs, levels and types of communication with their physicians, and sociodemographic characteristics. The information obtained from the paper-and-pencil survey helped me to assess the health needs of the elderly population. The findings and conclusions are discussed to compare the results of the research to previous findings described in the literature, draw

conclusions and implications, and offer recommendations associated with the self-medication of OTC NSAIDs.

Afolabi (2012) estimated that approximately 50% to 75% of health care expenses are associated with self-medication. However, self-medication is not without risks, despite the advantages associated with patient empowerment (Hughes et al., 2001). When individuals choose to self-medicate, they are engaging in help-seeking behavior (Klemenc-Ketis & Kersnik, 2011). Individuals who choose to self-medicate must be sure that the medications are appropriate for their chronic or recurrent conditions and have proven records of safety, quality, and efficacy (WHO, 1998). Such knowledge will not only help to bridge the gap between physicians and policymakers but also improve the targeting of specific patient populations to the extensive consumption of OTC NSAIDs by the elderly population. This knowledge also will help to increase the awareness of this population about the side effects of these medications.

The results of this study, which were based upon a cross-sectional survey of 124 participants, showed that the participants' awareness of adverse events associated with NSAIDs use was not associated with the sociodemographic variables, so Null Hypothesis 1 was supported. The results also showed that the participants' awareness of the risks was not related to their rates of consumption, so Null Hypothesis 2 also was retained. In addition, the results showed that awareness was related to patient-physician communication, so Alternative Hypothesis 3 was supported. In the final chapter, these findings are compared to results in the literature, conclusions and implications are drawn, and recommendations are offered.

Interpretation of the Findings

In some countries, the number of OTC medications is monitored through government-regulated systems (Balbuena et al., 2009). However, in the United States, OTC purchases are not monitored, thus making it difficult to identify the characteristics of the individuals who are the most likely to self-medicate and gain a better understanding of the different patterns of consumption within various geographic locations within the elderly population ages 65 years and older.

The results of this study were based upon collecting data from individuals from two senior citizen community centers in a metropolitan area in the Midwestern United States. The sociodemographics of the participants reflected the geographic area where the study was conducted and corresponded to similar statistics found across the Midwestern state by the U.S. Census Bureau (2012). The participants were 98.8% Caucasian/White), 60.5% had a level of education reflecting some college education or more, and 86.1% had an annual income of less than $50,000. Because of the sociodemographic characteristics of that particular Midwestern state, it would be beneficial for future research to be conducted in other geographic locations across the United States and include more diverse samples relevant to race/ethnicity. The participants in the current study did reflect the national population of 77.9% European American (U.S. Census Bureau, 2012). Despite the lack of diversity in the sample, the results will expand current understanding of the level of awareness among elderly individuals about their consumption of OTC NSAIDS and provide a foundation to improve levels of education, enhance the

dissemination of information, and identify gaps that future research initiatives might be able to address.

There has been insufficient data in the United States evaluating the relationship of levels of education, gender, ethnicity, marital status, living arrangements, and SES to OTC medication consumption, including the consumption of NSAIDs. An international study by Balbuena et al. (2009) highlighted the relationship between the consumption of OTC medications and sociodemographic characteristics. More than 50% of the participants consumed OTC medications within a 30-day period. In addition, self-medication was significantly greater among the participants who lived independently than among married couples ($p = .0274$) as well as those who were illiterate or had low levels of education than among participants who had graduated from high school ($p = .0036$).

You et al. (2011) conducted a cross-sectional phone survey of approximately 1,100 noninstitutionalized individuals in Hong Kong to evaluate their knowledge about the use of OTC medications and the associated risk factors. The results showed that participants who had no formal education or just a primary education (OR = 3.19; $p < .001$); had a secondary school education (OR = 1.50; $p = .035$); and were > 60 years of age (OR = 1.82; $p = .042$) were more likely to be less knowledgeable of self-medication and the risk factors associated with using OTC medications (You et al., 2011). In addition, the literature has reported that the consumption of NSAIDs is more frequent among females and increases with age (Lanas & Ferrandez, 2007).

The results of this study showed that of 75.8% the female and 76.6% of the male participants consumed NSAIDs. These results were similar to previous studies. For

example, Solomon (2003) conducted a study in Nigeria and found a high prevalence of self-medication among females (61.9%); Angeles (1992) reported similar results in Mexico (46%). The results of this study showed that 61% of the participants had attended at least some college courses and that 25.0% of the participants had earned a college degree. The level of education documented by Baig et al. (2012) indicated that 28.4% of the graduates in their study self-medicated.

Despite the fact that the majority of research compiled outside the United States has identified differences between sociodemographic characteristics and the percentage of people who engage in self-medication, the results of the current study indicated that none of the seven sociodemographic variables was associated with the participants' awareness of the risk of adverse events associated with OTC NSAIDs use. The results of this study identified the following frequency counts for OTC NSAIDs use: aspirin (37.1%), Tylenol (29.8%), and ibuprofen (17.7%). The number of NSAIDs brands used ranged from 0 (22.6%) to four or more (8.1%), and the number of NSAIDs days per month ranged from 0 (28.2%) to 22 to 30 (27.4%). In addition, frequency counts for the OTC NSAID categories were evaluated. The most commonly used NSAIDs categories were aspirin (37.1%) and acetaminophen (35.5%). The frequency of medications consumed might be dependent upon the dosage regimens of the OTC NSAIDs I question; however, the variability also might be the result of individuals deciding to self-medicate.

In a self-medication survey by Neafsey and Shellman (2001), the participants reported NSAIDs consumption, 46.9% reported taking NSAIDs for pain for 3 or more days at a time, and 36.7% reported taking NSAIDs daily for pain. The Sloan Survey,

which was conducted in the United States, found that more than twice as many people used acetaminophen (23%), ibuprofen (17%), or aspirin (17%) than any other OTC medications (as cited in McDonald et al., 2007). Similar results were reported in a survey in Finland, where 27% of the participants reported consuming OTC analgesics a few times each week (as cited in McDonald et al., 2007). However, based upon the literature, at least 25% of patients consuming NSAIDs have experienced adverse events, and many of these patients have required medical attention or possible hospitalization (Lanas & Ferrandez, 2007).

For the 88 respondents who answered the question about NSAIDs history, 73.9% reported taking the drugs for more than 6 months. According to the National Consumers League (2009), more than 175 million people in the United States are taking OTC medications for pain. Wilcox et al. (2005) contended that 36 million American are taking OTC pain medications daily and approximately 23 million are taking NSAIDs. Based upon the consensus reached by the American College of Cardiology, the American College of Gastroenterology and the American Heart Association, 70% of individuals in the elderly population consume NSAIDs once a week and 34% use them daily (as cited in American College of Cardiology Task Force, 2008). NSAIDs use is one of the most common causes of reported serious adverse reactions to drugs involving the gastrointestinal tract, cardiovascular system, liver, and kidneys (Barkin et al., 2010; Pineles & Parente, 2012). For example, acetaminophen, a common analgesic in the United States, has been reported as causing 78,414 emergency room visits and 26,000 hospital admissions annually (Budnitz et al., 2011; Lee, 2007; Nourjah et al., 2006).

Conaghan (2012) reported that NSAIDs consumption can be associated with an increased risk of cardiovascular events such as myocardial infarction, heart failure, and hypertension that are dependent upon the duration of exposure. Conaghan also found that the consumption of NSAIDs reported by the participants in the study resulted in gastrointestinal complications in approximately 30% of patients. In the current study, the participants were very aware of adverse effects associated with the consumption of NSAIDs, except for asthma. The most frequently known adverse effects were possible toxic interactions (81.5%) and gastrointestinal irritation (79.8%). A standard multiple regression model predicting awareness based upon the eight sociodemographic variables did not show any statistically significant difference and accounted for 6.3% of the variance in the respondents' awareness scores.

Researchers also have documented that NSAIDs can cause gastrointestinal complications (Tamer et al., 2000). The least endorsed awareness items in this study were personal experience of having side effects (16.9%) and awareness of the potential for asthma attack (25%). The results of the study showed no significant difference between awareness among the elderly population of the risk of adverse events and OTC NSAIDs consumption. No current literature in the United States has evaluated the rates of consumption and the risk associated with adverse events.

The quality of the physician-patient relationship and the level of communication between physicians and patients also have been shown to be related to patient outcomes (Funnell, 2011; Ratanawongsa et al, 2008; Verlinde et al., 2012). A higher quality of communication and trust influences patient satisfaction, compliance, and recall of

medical information. As a result, the health status among the elderly population can improve as communication with their physicians improves and becomes more honest and open. As demonstrated in the current study, 75% of the participants indicated that they had discussions with their physicians about the need to be award of the side effects of taking OTC NSAIDs.

The results of the current study associated with Research Question 3 identified a significant difference between the participants' awareness of the adverse events associated with OTC NSAIDs consumption and their levels of communication with their physicians. The results of the survey indicated that the participants had excellent levels of communication with their physicians, perhaps because they and their physicians recognized the value of consistently honest, open, informative, and bidirectional communication.

Support of the Conceptual Framework

The findings support the conceptual framework of the HBM, which is divided into three categories: (a) individual perceptions (i.e., perceived susceptibility to adverse event and the perceived seriousness of the adverse event); (b) modifying factors (i.e., demographic, sociopsychological, and structural variables); and (c) the likelihood of action (i.e., perceived benefits of preventative action). The HBM specifies the interactions of values and beliefs about health and their influences on choices.

In the current study, the participants were aware of the adverse events associated with the consumption of OTC NSAIDs and understood their susceptibility to such events related to consuming OTC NSAIDs. This high level of awareness was most likely the

result of the strong patient-physician levels of communication within this geographic location. The participants also had high levels of trust in their physicians, and they felt comfortable consuming OTC NSAIDs because their physicians were aware of their levels of consumption and understood that their medical status supported their consumption of OTC NSAIDs. Within the context of the medical needs of the elderly population, OTC NSAIDs consumption might not need to be changed.

The HBM provides the framework for people to change their behavior that can include such elements as mass media campaigns to raise awareness of adverse events associated with the consumption of OTC NSAIDS and improved communication between elderly patients and physicians. This model might influence individuals' beliefs about the potential for adverse reactions related to OTC NSAIDs consumption, their need to determine whether the threat is real enough to adopt behavior modification, and their need to improve levels of communication with their physicians.

Recommendations for Future Research

Future Research Questions

The results identified the importance of obtaining information to compare the findings to other geographic areas within the United States. The results also supported the need to educate the elderly population about the importance of strong patient-physician communication to understand the adverse side effects associated with the consumption of OTC NSAIDs. It also is important to focus on specific patient cohorts within the elderly population, such as individuals who have chronic renal insufficiency and other medical complications, to understand their level of awareness of the adverse effects associated

with the consumption of OTC NSAIDs. These different types of patient populations have comorbidities, so the impact of self-medicating with OTC NSAIDs will vary among these patients. Future researchers also might want to study possible measures that the health care system could take to improve the safety of OTC NSAIDs use.

Patients tend to self-manage their pain to improve their daily activities by consuming OTC NSAIDs, so future researchers might consider investigating and evaluating the sociodemographic factors (race/ethnicity, marital status, education, and income) associated with the consumption of multiple OTC NSAIDs. For example, conducting research over a wider geographic expanse might facilitate a more complete examination of sociodemographic differences. Determining the level of consumption of multiple OTC NSAIDs in the United States is difficult because no systems are in place to record such numbers, especially those associated with pharmacy claims or medical records. There is a lack of a well-accepted standardized measure to capture OTC consumption. It might be advantageous to research opportunities to develop and then implement technological systems to track consumption, a process that could help to increase the awareness of adverse events and decrease the number of preventable adverse events.

Best Practices to Improve Outcomes

Self-care that involves OTC medications, including NSAIDs, is very common among the elderly population. As the number of OTC medications continues to increase, so, too, does the risk of drug interactions and preventable adverse events. It is important to understand patterns of consumption to ensure individuals' health and reduce the risk of

preventable adverse events. It is important for physicians to communicate openly with their patients and routinely ask them about their OTC consumption of medications.

Patients need to be honest and tell their physicians exactly what OTC medications they are consuming. Enhanced lines of communication are beneficial, particularly when a patient has received a new diagnosis or a prescription for a medication that would alter a medical profile. Joint efforts with organizations such as the Centers for Education and Research on Therapeutics to conduct research and educate medical students, residents, research fellows, other allied health professionals, and the elderly population will help to advance the best use of OTC NSAIDS. Customized education campaigns could be an effective tool to promote their understanding. Collaborative efforts with representation from the elderly population, peer networking, and computer technology/social media could be used to reach the intended audience.

Additional education and research can provide guidance and direction to physicians, patients, and policymakers so that they can make informed decisions about their treatment options (self-medication vs. physician direction). Such research could include a value-tree method that could help to define the risks and benefits of consuming OTC NSAIDs. This type of research would facilitate an exploration of different possibilities and consequences in an effort to quantify decisions and help to build relationships with stakeholders to implement activities that support the elderly population. The results of this research can be used to identify gaps in awareness. Understanding the risks and benefits of medical therapies is critical to improving the

safety and effectiveness of their use and consumption and ensuring that patients and physicians have the knowledge to use medical therapies appropriately.

Social Change

The findings of this study are beneficial in showing stakeholders and policymakers the value of initiating educational campaigns that will improve individual choices in regard to the consumption of OTC NSAIDS and help to reduce preventable adverse events. Community programs based upon collaboration between health care professionals and organizations might help to reduce the number of adverse drug reactions. This quality initiative, along with the sharing of the results of this study with stakeholders at the local and national levels, will help to drive new initiatives and research in other areas area of the United States. It will support implementation of safer practices and strategies by increasing awareness associated with the consumption of OTC NSAIDs throughout the United States. The findings have implications for social change in that they will give different key stakeholders (i.e., health care professionals, health care organizations, and government agencies) more insight into the issue of preventable adverse events that might lead to the creation of more safety programs and informatics structural systems to monitor the consumption of OTC NSAIDs and improve lines of communication to protect the elderly population.

References

Abraham, N., El-Serag, H., Johnson, M., Hartman, C., Richardson, P., Ray, W., & Smalley, W. (2005). National adherence to evidence based guidelines for the prescription of NSAIDs. *Gastroenterology, 129*(4), 1171-1178.

Adams, R., Appleton, S., Gill, T., Taylor, A., Wilson, D., & Hill, C. (2011). Cause for concern in the use of non-steroidal anti-inflammatory medications in the community: A population-based study. Retrieved from http://www.biomedcentral.com/

Afolabi, A. (2012). Self-medication, drug dependency and self-managed health care. Retrieved from http://www.intechopen.com/

Aljadhey, H., Tu, W., Hansen, R., Blalock, S., Brater, D., & Murray, M. (2012). Comparative effects on NSAIDs on blood pressure in patients with hypertension. *Biomed Central, 12,* 1-10.

American College of Cardiology Task Force. (2008). ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risk of antiplatelet therapy and NSAID use. *Journal of the American College of Cardiology, 52*(18), 1502-1517.

Amoako, E., Campbell, L., & Malone, L. (2003). Self-medication with over the counter among elderly adults. *Journal of Gerontological Nursing, 29*(8), 100-115.

Antonov, K., & Isacson, D. (1996). Use of analgesics in Sweden: The importance of sociodemographic factors, physical fitness, health and health-related factors, and working conditions. *Sociology, Science, Medicine, 42*(11), 1473-1481.

Auta, A., Omale, S., Folorunsho, T., David, S., & Banwat, S. (2012). Medicine vendors: Self-medication practices and medicine knowledge. *North American Journal of Medical Sciences, 4*(1), 24-28. doi:10.4103/1947-2714.92899

Baig, Q., Muzaffar, D., Afaq, A., Bilal, S., & Iqbal, N. (2012). *Prevalence of self-medication among dental patients.* Retrieved from http://www.podj.com.pk/july_2012/26-podj-pdf

Balbuena, F., Aranda, A., & Figueras, A. (2009). Self-medication in older urban Mexicans: An observational, descriptive, cross-sectional study. *Drugs & Aging, 26*(1), 51-60. doi:10.2165/0002512-200926010-00004

Barkin, R., Beckerman, M., Blum, S., Clark, F., Koh, E., & Wu, D. (2010). Should NSAIDs be prescribed to older adults? *Drugs & Aging, 27*(10), 775-789. doi:10.2165/11539430-000000000-00000

Beyth, R. J., & Shorr, R. L. (2002). Principles of drug therapy in older patients: Rational drug prescribing. *Clinics in Geriatric Medicine, 18*(3), 577-592.

Bezreh, T., Laws, M., Taubin, T., Rifkin, D., & Wilson, I. (2011). Challenges to physician-patient communication about medication use: A window into the skeptical patient's world. *Patient Preference & Adherence, 6,* 11-18.

Boskey, E. (2008). Health belief model. Retrieved from http://std.about.com/

Boyle, A. (2011). Avoid NSAIDs after myocardial infarction. *Clinical Cardiology, 30,* 50-52.

Breedveld, F. (2003). Osteoarthritis: The impact of a serious disease. *Rheumatology, 43,* i4-i8.

Budnitz, D. S., Lovegrove, M. C., & Crosby, A. E. (2011). Emergency department visits for overdoses of acetaminophen containing products. *American Journal of Preventative Medicine, 40*(6), 585-592.

Carpenter, C. (2010). A meta-analysis of the effectiveness of health belief model variables in predicting behavior. *Health Communication, 25,* 661-669.

Cham, E., Hall, L., Ernst, A., & Weiss, S. (2002). Awareness and use of OTC pain medications: A survey of emergency department patients. *Southern Medical Journal, 95*(5), 529-535.

Chen, M., Wang, R., Schneider, J., Tsai, C., Jiang, D., & Lin, M. (2011). Using the health belief model to understand caregiver factors influencing childhood influenza vaccinations. *Journal of Community Health Nursing, 28,* 29-40.

Chutka, D., Takahashi, P., & Hoel, R. (2004). Inappropriate medications for elderly patients. *Mayo Clinic Proceedings, 79,* 122-139.

Conaghan, P. (2012). A turbulent decade for NSAIDs: Update on current concepts of classification, epidemiology, comparative efficacy and toxicity. *Rheumatology International, 32,* 1491-1502.

Cornoni-Huntley, J., Brock, D. W., & Ostfeld, A. M. (1986). *Established populations for epidemiological studies of the elderly resource data book.* Bethesda, MD: National Institution on Aging.

Crosby, R., DiClemente, R., & Salazar, L. (2006). *Research methods in health promotion.* San Francisco, CA: Jossey-Bass.

Cryer, B. (2005). NSAID associated deaths: The rise and fall of NSAID associated gastrointestinal mortality. *American Journal of Gastroenterology, 100,* 1694-1695.

Dedier, J., Stampfer, M. J., Hankinson, S. E., Willett, W. C., Speizer, F., & Curhan, G. (2002). Nonnarcotic analgesic use and the risk of hypertension in US women. *Hypertension, 40*(5), 601-603.

Ernst, E. (2003). Avocado-soybean unsaponifiables for osteoarthritis: A systemic review. *Clinical Rheumatology, 22,* 285-288.

Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-L. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavior Research Methods, 41*(4), 1149-1160.

Fendrick, A., Pan, D., & Johnson, G. (2008). OTC analgesics and drug interactions: clinical implications. *Osteopathic Medicine and Primary Care, 2,* 1-7.

Forman, J., Rimm, E., & Curhan, G. (2007). Frequency of analgesic use and risk of hypertension among men. *Archives of Internal Medicine, 167,* 394-399.

Fosbol, E., Follie, F., Jacabsen, S., Rasmussen, J., Sorensen, R., Schramm, T., … Gislason, G. (2010). Cause-specific cardiovascular risk associated with NSAIDs among healthy individuals. *Circulation Cardiovascular Quality Outcomes, 3,* 395-405.

Fraenkel, L., Wittink, D., Concato, J., & Fried, T. (2004). Informed choice and widespread use of antiinflammatory drugs. *Arthritis Rheumatology, 51*(2), 210-214.

Fredericks, S., & Sidani, S. (2012). Socio-demographics and health profile: Influence on self-care. *British Journal of Cardiac Nursing, 7,* 77-82.

Funnell, M. (2011). Physician-patient communication in diabetes care: Focus on injectables. *Journal of Family Practice, 60*(9), S29-S31.

Galvin, K. (1992). A critical review of the health belief model in relation to cigarette smoking behavior. *Journal of Clinical Nursing, 1,* 13-18.

Glanz, K., Lewis, F. M., & Rimer, B. K. (2002). Health behavior and health education. Retrieved from ww.answers.com/

Goswami, M., & Mahanta, S. (2012). *A study on attitude and achievement of higher secondary students in Mathematics in relation to their gender.* Retrieved from http://nime.hbcse.tifr.res.in/consequences/NIME-nc-2012-proceedings.pdf

Gregg, M. (2008). *Field epidemiology.* New York, NY: Oxford University Press.

Guvenc, G., Akyuz, A., & Acikel, C. (2010). Health Belief Model Scale for cervical cancer and Pap smear test: Psychometric testing. *Journal of Advanced Nursing, 67*(2), 428-437.

Harris Interactive. (2005). The public has doubts about the pharmaceutical industry's willingness to publish safety information about their drugs in a timely manner. Retrieved from http://www.harrisinteractive.com/

Haverhals, L., Lee, C., Siek, K., Darr, C., Linnebur, S., Ruscin, M., & Ross, S. (2011). Older adults with multi-morbidity: Medication management and process and design implications for personal health applications. *Journal of Medical Internet Research, 13*(2), e44.

Hazaveshei, S., Taghdisi, M., & Saidi, M. (2007). Applications of the health belief model for osteoporosis prevention among middle school girl students. Retrieved from http://www.educationalforhealth.net

Hochbaum, G. M. (1958). *Public participation in medical screening programs: A sociopsychological study.* Washington, DC: US Government Printing Office.

Hosseinpoor, A., Williams, J., Itani, L., & Chatterji, S. (2012). Socioeconomic inequality in domains of health: Results from the World Health surveys. *BMC Public Health, 12,* 198-206.

Hueberger, R. (2012). Polypharmacy and food-drug interactions among older persons: A review. *Journal of Nutrition in Gerontology and Geriatrics, 31*(4), 325-403.

Hughes, C., McElnay, J., & Fleming, G. (2001). Benefits and risks of self-medication. *Drug Safety, 24*(14), 1027-1037.

Hunter, L., Wood, D., & Dargan, P. (2011). The patterns of toxicity and management of acute nonsteroidal anti-inflammatory drug overdose. Retrieved from http://www.dovepress.com/

Indermitte, J., Reber, D., Beutler, M., Bruppacher, R., & Hersberger, K. (2007). Prevalence and patient awareness of selected potential drug interactions with self-medication. *Journal of Clinical Pharmacy and Therapeutics, 32,* 149-159.

Isacson, D., & Bingefors, K. (2002). Attitudes towards drugs. *Pharmacology World Science, 24*(3), 104-110.

Issel, M. (2009). *Health program planning and evaluation.* Sudbury, MA: Jones and Bartlett.

James, D., & French, D. (2008). The development of the Self-Medicating Scale: A scale to measure people's beliefs about self-medication. Retrieved from www.drmed.org/

Johnson, A. (1998). NSAIDs and blood pressure: Clinical importance for older patients. *Drugs & Aging, 12*(1), 17-27.

Johnson, L., Simons, A., Simons, J., Friedlander, Y., & McCallum, J. (1993). NSAIDs and HTN in the elderly: A community based cross sectional study. *British Journal Clinical Pharmacology, 35*(5), 455-459. doi:10.1111/j.1365-2125.1993.tb04169.x

Johnson, R., Roter, D., Powe, N., & Cooper, L. (2004). Patient race/ethnicity and quality of patient-physician communication during medical visits. *American Journal of Public Health, 94,* 2084-2090.

Kaufman, D. W., Kelly, J. P., Rosenberg, L., Anderson, T. E., & Mitchell, A. A. (2002). Recent patterns of medication use in the ambulatory adult population of the United States: The Slone Survey. *Journal of the American Medical Association, 287*(3), 337-344.

Klemenc-Ketis, Z., & Kersnik, J. (2011). The effect of demographic characteristics on self-medication: A cross sectional nationwide study from Slovenia. *Journal of Anthropology, 4,* 1237-1242.

Kovac, S., Hourston, T., & Weinberger, M. (2010). Inappropriate nonsteroidal anti-inflammatory drug use: Prevalence and predictors. *Journal of Patient Safety, 6*(2), 86-90.

Kovac, S., Saag, K., Curtis, J., & Allison, J. (2008). Association of health-related quality of life with dual use of prescription and over-the-counter nonsteroidal antiinflammatory drugs. Retrieved from http://onlinelibrary.wiley.com/

Lanas, A., & Ferrandez, A. (2007). Inappropriate prevention of NSAID-induced gastrointestinal events among long-term users in the elderly. *Drugs & Aging, 24*(2), 121-131.

Lanza, F., Chan, F., & Quigley, E. (2009). American College of Gastroenterology guidelines. *American Journal of Gastroenterology, 104,* 728-738.

Lee, W. M. (2007). Acetaminophen toxicity: Changing perceptions on a social/medical issue. *Hepatology, 46,* 966-970.

Lipschitz, D. A., Shmookler Reis, R. J., & Sullivan, D. H. (2001). The biology of aging. In T. E. Andreoli (Editor-in-Chief), *Cecil essentials of medicine* (5th ed., pp. 1001-1010). Philadelphia, PA: W. B. Saunders.

Lopez, R., & McMahan, S. (2007). College women's perception and knowledge of human papillomavirus and cervical cancer. *California Journal of Health and Promotion, 5*(3), 12-25.

Mackenzie, I., & MacDonald, T. (2010). Treatment of osteoarthritis in hypertensive patients. *Expert Opinion Pharmacotherapy, 11*(3), 1-11.

Maly, R., Frank, J., Marshall, G., DiMatteo, R., & Reuben, D. (1998). Perceived efficacy in patient-physician interactions (PEPPI) validation of an instrument in older persons. *Journal of the American Geriatrics Society, 46,* 889-894.

Mangoni, A., Jansen, P., & Jackson, S. (2009). Clinical pharmacology of ageing. In S. Jackson, P. Jansen, & A. Mangoni (Eds.), *Prescribing for elderly patients* (pp. 1-12). Chichester, UK: Wiley-Blackwell. doi:10.1002/9780470017975.ch1

Mann, D., Ponieman, D., Leventhal, H., & Halm, E. (2009). Predictors of adherence to diabetes medications: The role of disease and medication beliefs. *Journal of Behavioral Medicine, 32,* 278-284.

Maroon, J., & Bost, J. (2006). W-3 fatty acid (fish oil) as an anti-inflammatory: An alternative to NSAIDs for discogenic pain. *Surgical Neurology, 65*(4), 326-331.

Martins, A., Miranda, A., Mendes, Z., Soares, M., Ferreira, P., & Nogueira, A. (2002). Self-medication in a Portuguese urban population: A prevalence study. *Pharmacoepidmiology and Drug Safety, 11*(5)*,* 409-414.

McDonald, D., Interlandi, E., Wall, K., Lewchik, B., Polouse, L., Pace, N., … Li, L. (2007). Effect of reading additional safety information on planned use of over the counter analgesics. Retrieved from http://onlinelibrary.wiley.com/

Motola, D., Vaccheri, A., Silvani, M., Poluzzi, E., Bottoni, A., De Ponti, E., & Montanaro, N. (2004). Pattern of NSAID use in the Italian general population: A questionnaire-based survey. *European Journal of Clinical Pharmacology, 60*(10), 731-738.

National Consumers League. (2009). Understand your OTC drug facts and labels. Retrieved from www.natlconsumerleague.org/

Neafsey, P., & Shellman, J. (2001). Adverse self-medication practices of older adults with hypertension attending blood pressure clinics: Adverse self-medication practices. Retrieved from www.emedicine.medscape.com/

Neafsey, P., Strickler, Z., Shellman, J., & Chartier, V. (2002). An interactive technology approach to educate older adults about drug interactions arising from over-the-counter self-medication practices. Retrieved from http://onlinelibrary.wiley.com/

Ng, B., Kankanhalli, A., & Xu, Y. (2009). Studying users' computer security behavior: A health belief perspective. *Decision Support Systems, 46,* 815-825.

Noroozi, A., Jomand, T., & Tahmasebi, R. (2011). Determinants of breast self-examination performance among Iranian women: An application of the health belief model. *Journal of Cancer Education, 26*(2), 365-374. doi:10.1007/s13187-010-0158-y pp.365-74

Nourjah, P., Ahmad, S. R., & Karwoski, C. (2006). Estimates of acetaminophen associated overdoses in the United States. *Pharmacoepidemiology and Drug Safety, 15,* 398-405.

Okura, Y., Urban, L., & Mahoney, D. (2004). Agreement between self-report questionnaires and medical record data was substantial for diabetes, hypertension, myocardial infarction and stroke but not for heart failure. *Journal of Clinical Epidemiology, 57,* 1096-1103.

Olsen, A., Fosbol, E., Lindhardsen, J., Folke, F., Charlot, M., Selmer, C., … Gislason, G. (2011). Duration of treatment with nonsteroidal anti-inflammatory drugs and impact on risk of death and recurrent myocardial infarction in patients with prior myocardial infarction: A nationwide cohort study. Retrieved from http://circ.aha journals.org/

Papanikolaou, P., & Ioannidis, J. (2003). Awareness of the side effects of possessed medications in community setting. *European Journal Pharmacology, 5,* 821-827.

Peters, R., & Templin, T. (2010). Theory of planned behavior, self-care motivation, and blood pressure self-care. *Research and Theory for Nursing Practice, 24,* 172-186.

Pineles, L., & Parente, R. (2012). Using the theory of planned behavior to predict self-medication with over-the-counter analgesics. *Journal of Health Psychology,* 1-10. doi:10.1177/1359105312465912

Ratanawongsa, N., Roter, D., Beach, M., Laird, S., Larson, S., Carson, K., & Cooper, L. (2008). Physician burnout and patient-physician communication during primary care encounters. *Journal of General Internal Medicine, 23*(10), 1581-1588.

Rodriguez, L., Tacconelli, S., & Patrignani, P. (2008). Role of dose potency in the prediction of risk of myocardial infarction associated with NSAIDs in the general population. *Journal American College of Cardiology, 52,* 1628-1636.

Roumie, C., & Griffin, M. (2004). Over the counter analgesics in older adults: a call for improved labeling and consumer education. *Drugs & Aging, 21*(8), 485-498.

Schmidt, M., Christiansen, C., Mehnert, F., Rothman, K., & Sorensen, H. (2011). Non-steroidal anti-inflammatory drug use and risk of atrial fibrillation or flutter: Population based case-control study. *Biomedical Journal, 343,* d3450. doi:10.1136/bmj.d3450

Seager, J., & Hawkey, C. (2001). ABC of the upper gastrointestinal tract: Indigestion and non-steroidal anti-inflammatory drugs. *British Medical Journal, 323,* 1236-1239.

Shanks, L. C. (2009). Usefulness of the health belief model in predicting cardiac rehabilitation initiation. *Journal of Theory Construction and Testing, 13*(1), 33-36.

Singh, G., Miller, J., Huse, D., Pettitt, D., D'Agostino, D., & Russell, M. (2003). Consequences of increased systolic blood pressure in patients with osteoarthritis and rheumatoid arthritis. *Journal of Rheumatology, 30*(4), 714-719.

Solomon, R. (2003). Practice of self medication in Jimmatown, Nigeria. *Ethiopia Journal of Health Development, 17*(2), 111-116.

Sulaiman, W., Seung, O. P., & Ismail, R. (2012). Patient's knowledge and perception towards the use of non-steroidal anti-inflammatory drugs in rheumatology clinic Northern Malaysia. *Oman Medical Journal, 27*(6), 505-508. doi:10.5001/omj. 2012.121

Tamer, M., Moore, R., Reynolds, D., & McQuay, H. (2000). Quantitative estimation of rare adverse events which follow a biological progression: A new model applied to chronic NSAID use. *Pain, 85,* 169-182.

Taylor, R., Lemtouni, S., Weiss, K., & Pergolizzi, J. (2011). Pain management in the elderly: An FDA safe use initiative expert panel's view on preventable harm associated with NSAID therapy. Retrieved from http://www.hindawi.com/

Thom, D., Wong, S., Guzman, D., Wu, A., Penko, J., Miaskowski, C., & Kushel, M. (2011). Physician trust in the patient: Development and validation of a new measure. *Annals of Family Medicine, 9,* 148-154.

Thompson, F., & Caltabiano, M. L. (2010). The health belief model and dengue fever preventative behaviors: A pilot program. *International Journal of Health Promotion & Education, 48,* 9-19.

Torrible, S., & Hogan, D. (1997). Medication use and rural seniors. Who really knows what they are taking. *Canadian Family Physician, 43,* 893-898.

Trelle, S., Reichenbach, S., Wandel, S., Hildebrand, P., Tschannen, B., Villiger, P., & Juni, P. (2011). Cardiovascular safety of non-steroidal anti-inflammatory drugs: Network meta analysis. *Biomedical Journal, 342,* c7086-c7097. doi:10.1136/ bmj.c7086

U.S. Census Bureau. (2012). Population statistics. Retrieved from http://quickfacts. census.gov/

U.S. Department of Health and Human Services. (2009). *Organ-specific warnings: Internal analgesic, antipyretic, and antirheumatic drug products for over-the-counter human use: Labeling for products that contain acetaminophen.* Retrieved from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory Information/Guidances/UCM310477.pdf

U.S. Department of Health and Human Services. (2011). Aging statistics. Retrieved from www.aoa.gov/

van Staa, T., Rietbrock, S., Setakis, E., & Leufkens, G. (2008). Does the varied use of NSAIDs explain the differences in the risk of myocardial infarction? *Journal of Internal Medicine, 264,* 481-492.

van Wieringen, J., Harmsen, J., & Bruijnzeels, M. (2002). Intercultural communication in general practice. *European Journal of Public Health, 12,* 63-68.

Verlinde, E., De Laender, N., De Maesschalck, A., Deveugele, M., & Willems, S. (2012). The social gradient in doctor-patient communication. *International Journal for Equity in Health, 11,* 1-14.

Wertheimer, A., & Serradell, J. (2008). A discussion paper on self-care and its implications for pharmacists. *Pharmacy World Science, 30,* 309-315.

White, W. (2009). Defining the problem of treating the patient with hypertension and arthritis pain. *American Journal of Medicine, 122,* S3-S9.

Wilcox, C. M., Cryer, B., & Triadafilopoulos, G. (2005). Patterns of use and public perception of OTC pain relievers: Focus on nonsteroidal anti-inflammatory drugs. *Journal Rheumatology, 32,* 2218-2224.

World Health Organization. (1998). The role of the pharmacist in self-care and self-medication. Retrieved from http://apps.who.int/

You, J., Wong, F., Chan, F., Wong, E., & Yeoh, E. (2011). Public perception of the role of community pharmacists in self-medication and self-care in Hong Kong. Retrieved from http://www.biomedcentral.com/

Appendix A: OTC NSAIDs Survey

This survey is designed to better understand the use of OTC NSAIDS and patient-physician communication. Please select one response for each of the questions. Your responses will help us understand the over-the-counter non-steroidal anti-inflammatory (NSAID) medication use in different population groups.

(1)Age: _____ (Years)

(2) Sex

(a) Male

(b) Female

(3) Ethnicity

(a) White

(b) Black

(c) Hispanic

(d) Other

(4) Marital Status

(a) Married

(b) Widowed

(c) Single

(d) Divorce/Separated

(5) What is the highest level of education you have attained?

(a) Less than high school

(b) High School graduate

(c) Some college

(d) College graduate

(e) Graduate level degree

(6) Do you have a primary care physician?

(a) Yes

(b) No

(7) Do you live alone?

(a) Yes

(b) No

(8) What is your annual income?

(a) Income < $25,000

(b) Income ≥ $25,000 and ≤ $50,000

(c) Income > $50,000 and ≤ $ 100,000

Income > $100,000

9) Do you take over-the-counter NSAIDS?

(a) Yes

(b) No

If you answered yes to Question 9, which over-the-counter NSAIDS do you use?

(Please circle all that apply.)

Ibuprofen (Advil, Motrin, Nuprin, Medipren) Naproxen (Aleve) Aspirin

Acetaminophen (Tylenol) Other

10) What is the total numbers of over-the-counter NSAIDS you are currently taking?

0 1 2 3 4 5 6 7 8 9 10+

11) In the PAST MONTH, circle about how many DAYS you take OTC NSAIDS.

0 1-7 8-14 15-21 22 -30

12) In the PAST MONTH, circle about how many TIMES PER DAY you took OTC NSAID medication.

0 1 2 3 4 5 or more

13) Please circle how long how long you have been taking OTC NSAIDS.

1 WEEK 2-3 WEEKS 1 MONTH 2-3 MONTHS 4-6 MONTHS LONGER THAN 6 MONTHS

14) Do you discuss with your physician your use of over-the-counter NSAIDS?

(a) Yes

(b) No

15) Have you ever experienced any side effects as a result of taking over-the-counter NSAID medications?

(a) Yes

(b) No

If you answered "yes" to Question 15 how would you describe the side affects you experienced? Please choose one.

(a) Mild side effects.

(b) Moderate side effects

(c) Strong/painful side effects

(d) N/A

16) Were you aware that over-the-counter NSAIDS can possibly cause toxic interactions with other medications that you are taking?

(a) Yes

(b) No

17) Were you aware that therapeutic doses of Aspirin, Ibuprofen, and Naproxen can cause or worsen gastrointestinal irritation and bleeding especially in individuals with a history of gastrointestinal disease?

(a)Yes

(b) No

18) Were you aware that if you have asthma, Aspirin may increase the likelihood of asthma attack?

(a)Yes

(b) No

19) Were you aware that Aspirin, Ibuprofen, and Naproxen can cause kidney toxicity especially in individuals with a history of kidney disease?

(a)Yes

(b) No

20) Were you aware that in chronic doses, Acetaminophen can cause liver damage, especially in people with regular alcohol intake?

(a)Yes

(b) No

21) If you had been aware of the adverse side effects of over-the-counter NSAID medications when you started taking them, would it have made you think twice about how much you use them? Please select one answer.

(a) Yes, now that I am aware of over-the-counter NSAIDs' side effects, I wouldn't have used them at all.

(b) Yes, I would think twice about using them and take them with more caution.

(c) No, whether or not over-the-counter NSAIDS are harmful, I have no other option for pain relief.

The following questions will help understand the level of communication between yourself and your primary care physician. For each statement, please indicate your level of confidence.

How confident are you in your ability to:

22. Get a doctor to pay attention to what you have to say:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

23. Know what questions to ask your doctor:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

24. Get a doctor to answer all of your questions:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

25. Ask doctor questions about your chief health concern:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

26. Make the most of your visit with your doctor:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

27. Get a doctor to take your chief health concern seriously:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

28. Understand what a doctor tells you:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

29. Get a doctor to do something about your chief health concern:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

30. Explain your chief health concern to a doctor:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

31. Ask your doctor for more information if you do not understand what he/she said:

[0 = not confident at all, 10 = extremely confident]

0 1 2 3 4 5 6 7 8 9 10

THANK YOU FOR YOUR PARTICIPATION.

Appendix B: Permission to Use Instruments

--- On **Fri, 3/29/13, Amy Ernst <*AErnst@salud.unm.edu*>** wrote:

From: Amy Ernst <AErnst@salud.unm.edu>
Subject: Re: Michelle Popa: PhD Student Walden University: Publication Request
To: micki_vasile@yahoo.com
Date: Friday, March 29, 2013, 3:47 AM

It's fine with me. To publish the full survey in a journal would require permission from the journal though.
Best of luck
Amy

>>> MICHELLE POPA 03/28/13 6:12 PM >>>

Amy,

Thank you so much for your email. That is perfect. I would like to confirm that you will give me permission to use your instrument in my research. I look forward to hear from you. Thank you again for your time and support.

Regards,
Michelle

April 26, 2013

Michelle,

PEPPI is in the public domain and my official permission is not needed to use it--you just need to reference the original PEPPI validation study if you publish using it.

Best of luck with your research,
Rose Maly, MD, MSPH

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Curriculum Vitae

Michelle Popa, RD, LD, MSM, PhD (Candidate)

EDUCATION

- Expected 2014 PhD, Public Health: Epidemiology, Walden University, Minneapolis, MN
- 2001 MSM, College of Business Administration, Boston University, Boston, MA
- 1992 BS, Coordinated Program for Clinical Nutrition, Syracuse University, Syracuse, NY

PROFESSIONAL EXPERIENCE

- 2013-Present AstraZenaca

  Global medical affairs leader: Diabetes and metabolism (product launch & advocacy)
- 2011-2013 Guerbet

  Medical Science Liaison Manager North America
- 2010 Science Oriented Solutions: NicOx (Company closed U.S. operations: product not approved by the FDA)

  Global and medical/clinical affairs/clinical trials: Senior medical science liaison (West USA)
- 2007-2010 Baxter Healthcare

  Global and medical/clinical affairs/clinical trials: Medical science liaison: U.S. region: Team leader
- 2003-2007 Sanofi-Aventis, Fort Lauderdale, FL

  Specialty sales/hospital - Cardiovascular business unit

- 2001-2003 Ventiv U.S. Healthcare (Contract - Noven Pharmaceuticals), Dade County, Homestead, Florida Keys, FL

  Pharmaceutical representative

PUBLICATIONS

- 1993 Cardiac Nutrition Book
- 1994 Book on HIV/AIDS and Nutrition
- 1995 Nursing Spectrum Magazine

AWARDS

- 1995 Young Distinguished Dietitian Miami
- 1996 Young Distinguished Dietitian in Florida